UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

INTERNATIONAL BROTHERHOOD OF TEAMSTERS LOCAL 456 HEALTH AND WELFARE TRUST FUND and UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, on behalf of themselves and all others similarly situated,	
Plaintiffs,	**No. 10-cv-01692-RJD-RLM**
v.	
QUEST DIAGNOSTICS INCORPORATED and NICHOLS INSTITUTE DIAGNOSTICS,	
Defendants.	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND MOTION TO STRIKE

Respectfully submitted,

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INTRODUCTION

The named Plaintiffs, two union health and welfare funds, allege that defendant Nichols Institute Diagnostics ("NID") manufactured and sold certain defective diagnostic laboratory test kits to clinical laboratories. (Am. Compl. ¶ 28). Plaintiffs — who never purchased any of the kits themselves nor reimbursed any laboratories for their kit purchases — purport to bring this lawsuit as a class action on behalf of all entities in the United States who, for purposes other than resale, purchased, reimbursed and/or paid for the allegedly defective kits. (Am. Compl. ¶¶ 6, 63–65).

Defendants NID and Quest Diagnostics Incorporated ("Quest Diagnostics") respectfully submit this memorandum in support of their motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). Quest Diagnostics must be dismissed from this action as Plaintiffs have utterly failed to plead any facts whatsoever establishing any plausible claim for relief against that defendant. Plaintiffs' purported RICO claims fail to satisfy the rigorous pleading requirements of that statute. Further, both the RICO claims as well as the state law and common law claims are time-barred. In addition, the complaint, even after amendment, fails to set forth any viable claims for relief under Plaintiffs' various state law and common law theories.

ARGUMENT

I. THE COMPLAINT, WHICH HAS ALREADY BEEN AMENDED ONCE, STILL FAILS TO STATE ANY CLAIM UPON WHICH RELIEF MAY BE GRANTED AGAINST DEFENDANT QUEST DIAGNOSTICS

NID is sued separately as a "wholly owned subsidiary" of Quest Diagnostics, and thus the two defendants are legally separate corporate entities. (Am. Compl. ¶¶ 19, 23). It is black letter law that the existence of a parent-subsidiary relationship between two corporations will not, without more, make the parent liable for the acts of its subsidiary. *See, e.g., United States v. Bestfoods*, 524 U.S. 51, 61–62 (1998); *Sterling v. Interlake Indus. Inc.*, 154 F.R.D. 579, 587–

88 (E.D.N.Y. 1994). There are no allegations of corporate veil piercing. *See, e.g., Fletcher v. Atex, Inc.*, 68 F.3d 1451, 1458 (2d Cir. 1995) (setting forth the factors that must be alleged and proved to pierce the corporate veil, none of which are even alleged in Plaintiffs' pleading, much less supported by factual averment). Accordingly, in order to state a claim for relief against Quest Diagnostics, Plaintiffs must allege facts sufficient to satisfy the standards established in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

Here, however, even after amendment, Plaintiffs have failed to allege a single fact indicating that Quest Diagnostics, as opposed to NID, had any role whatsoever in the manufacture or sale of any allegedly defective kits. The only fact alleged regarding Quest Diagnostics appears in paragraph 46, where it is asserted that in 2001 "in conjunction with Quest," NID published an abstract (which is not alleged to be inaccurate or misleading in any way) in the publication of the Endocrine Society. Beyond that meaningless allegation, the amended complaint is barren of a single factual averment regarding any wrongful acts by Quest Diagnostics.

The Supreme Court has made clear that in deciding a motion to dismiss, "'naked assertion[s]' devoid of 'further factual enhancement'" and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to state a claim. *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 557). Further, to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570); *accord Vaughn v. Air Line Pilots Assoc., Int'l*, 604 F.3d 703, 709 (2d Cir. 2010); *Pocino v. Culkin*, No. 09-cv-3447, 2010 WL 3516219, at *1 (E.D.N.Y. Aug. 31, 2010)

(Dearie, C.J.). To avoid dismissal, the pleading must allege facts that, when assumed as true, evince "more than a sheer possibility that a defendant has acted unlawfully" and affirmatively demonstrate that Plaintiffs are entitled to relief. *See Iqbal*, 129 S. Ct. at 1949. Here, after two attempts, Plaintiffs are unable to allege any acts whatsoever demonstrating any right to relief against Quest Diagnostics.

In their pre-motion letter Plaintiffs asserted that because the amended complaint references a *qui tam* action filed against Quest Diagnostics as well as NID and refers to a civil settlement by Quest Diagnostics in that matter (Am. Compl. ¶¶ 57–62), this somehow rescues the present action. That is plainly not the law. It is undisputed that Quest Diagnostics made no admission in the settlement, a fact conceded by Plaintiffs' counsel at the pre-motion hearing held on December 9, 2010. Most significantly, it is well-settled in this circuit that "[p]aragraphs in a complaint which are 'based on, or rely on, complaints in other actions that have been dismissed, settled, or otherwise not resolved are, as a matter of law, immaterial'" and should be stricken. *Footbridge Ltd. Trust v. Countrywide Home Loans, Inc.*, No. 09 Civ. 4050, 2010 WL 3790810, at *5 (S.D.N.Y. Sept. 28, 2010) (quoting *RSM Prod. Corp. v. Fridman*, 643 F. Supp. 2d 382, 403 (S.D.N.Y. 2009)); *see also RSM Production*, 643 F. Supp. 2d at 403 (S.D.N.Y. 2009) (granting motion to dismiss, finding that such matters "could have no possible bearing on the dispute before the court"); *Dent v. U.S. Tennis Ass'n*, No. CV-08-1533, 2008 WL 2483288, at *4 (E.D.N.Y. June 17, 2008) (Pohorelsky, M.J. sitting for Dearie, C.J.) (striking references in complaint to settlement agreements between defendant and the New York Attorney General's office); *In re Merrill Lynch & Co., Inc. Research Reports Sec. Litig.*, 218 F.R.D. 76, 78–79

(S.D.N.Y. 2003).[1/] Accordingly, because the settlement of the *qui tam* action is not even to be considered, Plaintiffs have presented no basis for proceeding against Quest Diagnostics.

Plaintiffs' final argument in their pre-motion letter is that Quest Diagnostics has "successor liability" for NID. However, there is not a single factual allegation in the complaint, even as amended, to support such an assertion, and no claim of successor liability appears anywhere in the pleading. To the contrary, NID is sued as a separate defendant. (Am. Compl. ¶ 23). As a matter of law, successor liability can only arise when a company purchases the *assets* of another company and where at least one of the following four factors apply: (i) the buyer has expressly assumed liability; (ii) the purchase resulted in a *de facto* merger or consolidation; (iii) the purchase resulted in a mere continuation of the predecessor under a different name; or (iv) fraud. *See, e.g.*, *Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 45 (2d Cir. 2003). Here, where Quest Diagnostics is not alleged to, and did not, purchase the assets of NID, and NID is instead a wholly-owned subsidiary, Quest Diagnostics cannot be held liable under a successor liability theory under any circumstances. *See, e.g.*, *id.* (in an acquisition of stock transaction, liability of acquiring company can only be established by piercing corporate veil). Further, Plaintiffs have failed to allege any facts demonstrating the existence of any of the four factors necessary to prove successor liability. Accordingly, Plaintiffs' argument is wholly without merit.

In sum, because Plaintiffs have failed, even after amendment, to allege any facts whatsoever establishing any basis for relief against Quest Diagnostics, that defendant must be dismissed from this case.

1/ Defendants have incorporated a motion to strike these offending paragraphs into their motion to dismiss.

II. THE FIRST CAUSE OF ACTION FAILS TO STATE A CLAIM FOR VIOLATION OF RICO § 1962(c)

"It has been suggested that 'the civil provisions of [RICO] are the most misused statutes in the federal corpus of law.'" *West 79th Street Corp. v. Congregation Kahl Minchas Chinuch*, No. 03 Civ. 8606, 2004 WL 2187069, at *5 (S.D.N.Y. Sept. 29, 2004) (quoting *Spoto v. Herkimer County Trust*, No. 99 Civ. 1476, 2000 WL 533293, at *1 (N.D.N.Y. Apr. 27, 2000)). This District has aptly underscored the close scrutiny with which Plaintiffs' First Cause of Action — the only federal statute pleaded — should be evaluated: "RICO claims 'must be reviewed with appreciation of the extreme sanctions it provides so that actions traditionally brought in state courts do not gain access to treble damages and attorneys fees in federal court simply because they are cast in terms of RICO violations.'" *Republic of Columbia v. Diageo N. Am., Inc.*, 531 F. Supp. 2d 365, 382–83 (E.D.N.Y. 2007) (quoting *Leung v. Law*, 387 F. Supp. 2d 105, 112–13 (E.D.N.Y. 2005)); *see also Tuscano v. Tuscano*, 403 F. Supp. 2d 214, 226 (E.D.N.Y. 2005) ("Because '[c]ivil RICO is an unusually potent weapon[,] "courts should strive to flush out frivolous RICO allegations at an early stage in the litigation."'") (quoting *Katzman v. Victoria's Secret*, 167 F.R.D. 649, 655 (S.D.N.Y. 1996)). Because even after amending their RICO theory Plaintiffs have failed either (i) to allege a RICO "enterprise" that is distinct from the defendants' regular business operations as required by 18 U.S.C. § 1962(c), or (ii) to identify the sources or substance of any particularized predicate acts of racketeering as required by Fed. R. Civ. P. 9(b), the First Cause of Action must be dismissed.

A. Plaintiffs Have Failed To Plead An "Enterprise" Distinct From The Defendant "Persons" As Required By § 1962(c).

RICO "'has as its purpose the elimination of the infiltration of organized crime and racketeering into legitimate organizations operating in interstate commerce.'" *Crab House of Douglaston, Inc. v. Newsday, Inc.*, 418 F. Supp. 2d 193, 202 (E.D.N.Y. 2006) (citation omitted).

Accordingly, § 1962(c) of RICO draws a crucial distinction between the requisite RICO "enterprise" and the defendant RICO "person" who infiltrates that enterprise and uses it to engage in racketeering activities.[2/] This Circuit has squarely and repeatedly held that the enterprise cannot be the same entity as the defendant RICO person. *Riverwoods Chappaqua Corp. v. Marine Midland Bank*, 30 F.3d 339, 344 (2d Cir. 1994). While a corporation and its subsidiaries may be an enterprise for RICO purposes, the infiltrating defendant RICO person committing the illegal racketeering acts must be an entity distinct from the enterprise. Conversely, a corporate entity may be held liable as a defendant RICO person but only "where it associates with others to form an enterprise that is sufficiently distinct from itself." *Id.*; *see also Rush v. Oppenheimer & Co.*, 628 F. Supp. 1188, 1193 (S.D.N.Y. 1985); *Black Radio Network, Inc. v. NYNEX Corp.*, 44 F. Supp. 2d 565, 580 (S.D.N.Y. 1999) ("The enterprise . . . must... be an entity separate from the pattern of racketeering activity in which it engages . . . . [A] corporate entity may not be both the enterprise and the person who conducts the affairs of the enterprise through racketeering."). Where all the entities that make up the enterprise are also all the defendant RICO persons — precisely the case here — the distinctiveness requirement of § 1962(c) is not satisfied. *City of New York v. Cyco.Net, Inc.*, 383 F. Supp. 2d 526, 547–52 (S.D.N.Y. 2005).

The Second Circuit Court of Appeals has made it clear that a parent corporation and its wholly-owned subsidiaries, even though they are legally separate entities, cannot for RICO purposes be cast as both the defendant infiltrating RICO "person" and the alleged infiltrated RICO "enterprise." This is because there is not sufficient distinction between the enterprise and the "infiltrating" person when the members of the enterprise are in fact so closely affiliated.

[2/] 18 U.S.C. § 1962(c) prohibits "any person employed by or associated with any enterprise ... to conduct ... such enterprise's affairs through a pattern of racketeering activity...."

Discon, Inc. v. NYNEX Corp., 93 F.3d 1055, 1063–64 (2d Cir. 1996), *rev'd on other grounds*, 525 U.S. 128 (1998); *see also Riverwoods Chappaqua Corp*, 30 F.3d at 344 (a RICO plaintiff cannot allege a RICO enterprise that consists merely of a corporate defendant associated with its own employees or agents carrying on the regular affairs of the defendants); *Rush*, 628 F. Supp. at 1194 (dismissing § 1962(c) claim which had cast corporation as "person" and its New York City office as "enterprise," holding that "carving out a 'piece' of a corporate defendant to create a distinct 'enterprise' will not satisfy the pleading of a civil RICO claim'"); *Protter v. Nathan's Famous Sys., Inc.*, 925 F. Supp. 947, 955–56 (E.D.N.Y. 1996) (dismissing § 1962(c) claim because corporation cast as "enterprise" is not distinct from corporate officers alleged as "persons").

Plaintiffs have effectively acknowledged that they are wholly unable to meet this distinctiveness requirement. In their initial complaint Plaintiffs alleged that the enterprise consisted solely of defendant RICO persons Quest Diagnostics and its wholly-owned subsidiary NID (Compl. ¶ 75). Recognizing the inadequacy of this pleading in light of the Second Circuit's holding in *Discon*, Plaintiffs amended their complaint to now allege that the enterprise included not only Quest Diagnostics and NID, the named RICO person defendants, but also "other as yet unknown marketing and distribution agents." (Am. Compl. ¶ 75). This attempted rescue effort is wholly unavailing for two reasons. First, its rank generality fails to satisfy the particularity requirements of Fed. R. Civ. P. 9(b). *See infra* at Part II. B; *see also Black Radio Network, Inc.*, 44 F. Supp. 2d at 581 & n.6 (rejecting attempt to add "certain unnamed long-distance carriers" and holding that "[p]laintiffs are not entitled … to conduct discovery to discover facts that would establish a RICO enterprise.").

Second, this cursory addition of corporate "agents" — none of whom are alleged to have done anything more than assist their principals to sell the kits — fails to satisfy the RICO distinctiveness requirement. Second Circuit law expressly holds that agents acting on behalf of their principals' business remain substantially identical to their principals for RICO purposes, and thus do not constitute the distinction between RICO enterprise and defendant RICO person required by § 1962(c). *See Discon*, 93 F.3d at 1064 ("Discon's reference to unnamed 'attorneys, accountants and other agents' as part of the enterprise does not alter this analysis."); *Riverwoods*, 30 F.3d at 344 (RICO enterprise cannot consist merely of the corporate defendants and its agents carrying on the regular affairs of the defendants); *see also In re Parmalat Sec. Litig.*, 479 F. Supp. 2d 332, 346–47 (S.D.N.Y. 2007) ("[T]he Bank's inclusion of 'affiliates and subsidiaries located around the world,' 'culpable employees, directors and officers,' and Parmalat's counsel Zini do not distinguish the enterprise from the person. Nor does the reference to the 'variety of third-party entities' change anything."); *Lorentzen v. Curtis*, 18 F. Supp. 2d 322, 332 (S.D.N.Y. 1998) (dismissing § 1962(c) claim because defendant companies were not distinct from alleged enterprise made up of the companies and their law firms as "participating agents" in the alleged fraud).[3/]

3/ Plaintiffs' citation in their pre-motion letter to *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158 (2001), is unavailing. In a decision narrowly limited to its particular facts, the Court ruled that where the defendant boxing promoter was both the only shareholder and employee of his corporation and conducted the affairs of that sole proprietorship in a RICO-prohibited way, a § 1962(c) violation may be found. The Court went out of its way to specifically note that the Second Circuit precedent in cases such as *Discon* and *Riverwoods* concerned very different circumstances which were in no way being considered by the Court. *Id.* at 164. Subsequent to *King*, the courts in this circuit continue to follow *Discon* as controlling authority and dismiss § 1962(c) claims where, as here, the alleged enterprise consists of a parent and its subsidiary corporations or a corporation and its affiliates or agents engaged in their regular business activities. *See, e.g., Cyco.net*, 383 F. Supp. 2d at 547–52; *Crab House of Douglaston*, 418 F. Supp. 2d at 205–06; *In re Parmalat Sec. Litig*, 479 F. Supp. 2d at 346–47; *DeFazio v. Wallis*, 500 F. Supp. 2d 197, 209–10 (E.D.N.Y. 2007); *Feinberg v. Katz*,No . 99 Civ 0045, 2005 WL 2990633, at *7–8 (S.D.N.Y. Nov. 7, 2005).

Accordingly, because after two attempts Plaintiffs have been wholly unable to allege a RICO enterprise that is distinct from the defendant RICO persons, the First Cause of Action must be dismissed for failing to state a claim for relief under § 1962(c).

B. The First Cause of Action Must Also Be Dismissed For Failure To Plead Any Predicate Acts With Requisite Particularity.

In this circuit, where — as here — the alleged predicate acts supporting the RICO claim are based on mail or wire fraud, such acts must be pleaded with particularity under Fed. R. Civ. P. 9(b):

> When the predicate acts of a civil RICO claim are grounded in fraud, the concerns associated with pleading fraud with particularity take on even greater importance. Accordingly, a claim of mail or wire fraud must specify the content, date and place of any alleged misrepresentation and the identity of the persons making them.

Mathon v. Feldstein, 303 F. Supp. 2d 317, 322–23 (E.D.N.Y. 2004) (citing *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172–73 (2d Cir. 1990)) (internal citation omitted); *see also Anatian v. Coutts Bank (Switzerland) Ltd.*, 193 F.3d 85, 88 (2d Cir. 1999); *DeFazio*, 500 F. Supp. 2d at 204. In their undifferentiated references to "Defendants' use of the mails and wires," or "Defendants' scheme," or "Defendants' course of fraudulent conduct," Plaintiffs have failed to meet *every* prong of the particularity standard itemized in *Mathon*. (*See, e.g.*, Am. Compl. ¶¶ 81, 83, 60). Nowhere in their purported inventory of "thousands" of predicate acts of fraud do Plaintiffs specify even *one* source, date or place, or quote from — or even summarize the substance of — any particular communication that allegedly constituted mail or wire fraud. *Id.* ¶ 81. Instead, Plaintiffs' entire portrayal of the alleged RICO scheme "vaguely attributes the alleged fraudulent statement to 'defendants,'" a tactic long ago rejected in this circuit and others. *See, e.g., Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993).

The failure to satisfy Rule 9(b)'s requirements is even more glaring with regard to Quest Diagnostics. Where there are multiple defendants, Rule 9(b) requires that the complaint inform *each* defendant of the nature of its participation in the alleged fraud. *See, e.g., DiVittorio v. Equidyne Extractive Indus., Inc.*, 822 F.2d 1242, 1247 (2d Cir. 1987). Plaintiffs' complaint, even after amendment, plainly fails to do so. Quest Diagnostics never is identified as a source or facilitator of any fraudulent communications or acts. Instead, Plaintiffs refer to (unspecified) "communications with and among enterprise participants," but *only* regarding "the defective Nichols Kits" (Am. Compl. ¶ 81 (a), (b), (f) & (g)), and then admit that *all* of those kits were "developed," "launched," "manufactured, marketed and sold" *only* by NID. *Id.* ¶¶ 37, 41, 52 & 64(a). Never is Quest Diagnostics identified as a participant in those kit-selling efforts. Similarly, Plaintiffs' generalized allegation of wrongful "communications with patients and Class Members" again is limited to misrepresentation about the "defective Nichols Kits," *id.* ¶ 81(c), and again is amplified only by allegations grouped under the telling headings, "*Nichols'* Fraudulent Marketing of PTH [and Other Advantage Diagnostic] Kits. *Id.* ¶¶ 47–56 (emphasis added). Indeed, Quest Diagnostics is not provided with any notice whatsoever as to what fraudulent conduct it is charged with. Accordingly, Plaintiffs' amended complaint fails utterly to meet the requirements of Rule 9(b).

Plaintiffs' sole effort at rebuttal in their pre-motion letter was to assert that Defendants are seeking to hold them to a pleading standard of "absolute precision," and to refer to a case outside of this circuit, *In re Rockefeller Center Properties, Inc. Securities Litigation*, 311 F.3d 198, 216 (3d Cir. 2002). In fact, Defendants do not seek to hold Plaintiffs to any standard beyond that stated in Rule 9(b) and the decisions of this Circuit, which metric Plaintiffs have wholly failed to satisfy. Further, in the very authority Plaintiffs do cite, the Third Circuit

expressly held that in pleading fraud, Rule 9(b) requires that the claim must be supported "with all of the essential factual background that would accompany 'the first paragraph of any newspaper story — that is, the 'who, what, when, where and how' of the events at issue.'" *Id.* at 217 (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997)). It is precisely such facts that Plaintiffs have failed to set forth.

Because Plaintiffs have "simply regurgitated the generic requirements of the RICO statute and the mail and wire fraud statutes" without setting forth any specifics regarding any alleged fraudulent communications, they have failed to satisfy the strictures of Fed. R. Civ. P. 9(b). *Bologna v. Allstate Insurance Co.*, 138 F. Supp. 2d 310, 322 (E.D.N.Y. 2001). Accordingly, for this reason as well their attempt to state a claim under RICO § 1962(c) must be dismissed.

III. THE SECOND CAUSE OF ACTION FAILS TO STATE A CLAIM FOR VIOLATION OF RICO § 1962(d)

By their Second Cause of Action, Plaintiffs plead no new or additional facts. Instead, they simply proffer an ostensibly separate claim that "Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c)." (Am. Compl. ¶ 93). That count, however, impermissibly substitutes empty redundancy for new substance, conceding that the alleged conspiracy's only object was "to conduct or participate in, directly or indirectly, the conduct of affairs of the Defective Kits Enterprise," and that the "overt and predicate fraudulent racketeering acts in furtherance of the conspiracy" are only those "as described above." *Id.* ¶¶ 93, 94 (apparently referring back to ¶ 81 of the First Cause of Action). Because this count adds nothing beyond a bare-bones allegation of conspiracy to violate § 1962(c), and because as shown above there is no well-pleaded claim for violation of that statute, Plaintiffs' claim under § 1962(d) must be dismissed as well. *See, e.g., Discon*, 93 F.3d at 1064 ("Since we have held

that the prior claims do not state a cause of action for substantive violations of RICO, the present claim does not set forth a conspiracy to commit such violations."); *West 79th Street Corp.*, 2004 WL 2187069, at *16.

IV. PLAINTIFFS' CLAIMS ARE BARRED BY THE APPLICABLE STATUTES OF LIMITATION

This action was commenced on April 15, 2010. Plaintiffs admit that all of the kits claimed to be defective were in fact recalled by NID in 2005. (Am. Compl. ¶ 59). The recall notices sent to the members of the purported plaintiff class in 2005, copies of which are attached as Exhibit 1 to the Appendix,[4/] expressly advised the laboratories that the kits did not perform as represented in the accompanying NID Directional Inserts, did not correlate to the industry-standard IRMA kits as NID had promised, and had problems with accuracy and reliability, which are precisely the defects and misrepresentations complained of by Plaintiffs. *See id.* ¶¶ 47–49, 50, 53–54). The notices advised that the FDA was similarly aware of the recall actions.

Following the recalls, on June 16, 2005, NID notified the purported class members that it was placing a hold on *all* of its products, which hold was also reported in the 2005 Form 10-K filed with the SEC on February 28, 2006. (*See* Exhibit 2 to the Appendix containing pertinent portions of the 10-K). The FDA itself in 2005 issued public Enforcement Bulletins on its website (http://www.fda.gov/Safety/Recalls/EnforcementReports/2005) regarding the recalls and the reasons therefor, copies of which are attached as Exhibit 3 to the Appendix. These bulletins advised that the kits were being recalled because, *inter alia*, "[p]erformance does not meet claims

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4/ In deciding a motion to dismiss, the Court may consider the factual allegations in the pleadings, exhibits to the complaint or documents or statements incorporated by reference, matters of which judicial notice may be taken, public disclosure documents required by law to be filed, news articles, and documents in Plaintiffs' possession or of which they had knowledge and relied on in bringing suit. *See Brass v. Am. Film Techs., Inc.*,9 87 F.2d 142, 150 (2d Cir. 1993); *see also Rothman v. Gregor*,2 20 F.3d 81, 88–89 (2d Cir. 2000); *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002); *Zdziebloski v. Town of East Greenbush*, 101 F. Supp. 2d 70, 71 (N.D.N.Y. 2000).

in the Directional Insert concerning correlation with the IRMA ACTH assay." (*Compare* Am. Compl. ¶¶ 47–49).

In its public SEC filings for 2004 and 2005, also available on the Internet, Quest Diagnostics publicly disclosed that the United States Attorney's Office had commenced a criminal investigation into the manufacture and marketing of the test kits. (Pertinent portions of these filings are attached as Exhibit 4 to the Appendix). Thus, the Form 10-Q filed on October 29, 2004, disclosed:

> On October 25, 2004, the Company and its test kit manufacturing subsidiary, Nichols Institute Diagnostics, each received a subpoena from the United States Attorney's office for the Eastern District of New York. The subpoenas seek the production of various business records, including documents related to tests cleared by the Food and Drug Administration for parathyroid hormone, or PTH levels.
>
> * * *
>
> [T]he Company understands that there may be pending qui tam claims brought by former employees or other "whistle blowers", or other pending claims as to which the Company has not been provided with a copy of the complaint and accordingly cannot determine the extent of any potential liability.

The Form 10-K for 2004, filed on March 10, 2005, reported:

> We have also received subpoenas from the United States Attorney's Office for the Eastern District of New York requiring the production of various business records including documents related to parathyroid hormone testing and parathyroid hormone test kits manufactured by our subsidiary Nichols Institute Diagnostics.

The Form 10-K for 2005, filed on February 28, 2006, provided further detail:

> During the fourth quarter of 2004, Quest Diagnostics Incorporated and Nichols Diagnostic Institute (NID), our test kit manufacturing subsidiary, each received a subpoena from the United States Attorney's Office for the Eastern District of New York. Quest Diagnostics and NID have been cooperating with the United States Attorney's Office. In connection with such cooperation, we have been providing information and producing various business

> records of NID and Quest Diagnostics, including documents related to testing and test kits manufactured by NID. This investigation by the United States Attorney's Office could lead to civil and criminal damages, fines, and penalties and additional liabilities from third party claims.

The media also reported on the criminal investigation into the manufacture of the kits. Attached as Exhibit 5 to the Appendix are articles published by Reuters News service and by the Newark Star-Ledger on October 28 and 29, 2004, respectively, which were available on the Internet. Both media sites reported on the commencement of the criminal investigation into the test kits made by NID and the fact that the companies were reporting having been served with subpoenas by the United States Attorney's Office.

A. Plaintiffs' Purported RICO Claims Are Time-Barred.

Civil RICO claims are subject to a four-year statute of limitations. *Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156 (1987). A RICO claim accrues when the plaintiff discovers, or should have discovered, the RICO injury. *Tho Dinh Tran v. Alphonse Hotel Corp.*, 281 F.3d 23, 35 (2d Cir. 2002), *overruled on other grounds by Slayton v. Am. Express Co.*, 460 F.3d 215 (2d Cir. 2006). The statute of limitations begins to run "when [Plaintiffs] have actual or inquiry notice of the injury." *In re Merrill Lynch Ltd. P'ships Litig.*, 154 F.3d 56, 60 (2d Cir. 1998). "The limitations period for a fraud-based RICO action commences when Plaintiffs are placed on notice of facts which should arouse suspicion." *In re Integrated Res., Inc., Real Estate Limited P'ships Sec. Litig.*, 851 F. Supp. 556, 567 (S.D.N.Y. 1994). The claim accrues not when plaintiff has all of the facts regarding the fraud, but rather "facts sufficient to create a duty to investigate further into the matter." *Id.* at 568. The question is whether a reasonable person in plaintiff's shoes would have inquired further into the matter. *Meadowbrook-Richman, Inc. v. Associated Fin. Corp.*, 325 F. Supp. 2d 341, 362–63 (S.D.N.Y. 2004). The issue involves an examination of when Plaintiffs received information sufficient to

alert a reasonable person to the probability that they had been misled and whether they responded to such notice with reasonable diligence. *Id.*

The question of inquiry notice need not be left to a finder of fact. *In re Merrill Lynch Ltd. P'ships Litig.*, 154 F.3d at 60; *Cohain v. Klimley*, No. 08 Civ. 5047, 2010 WL 3701362, at *5 (S.D.N.Y. Sept. 20, 2010) ("'Whether a plaintiff was placed on inquiry notice is analyzed under an objective standard. This objective determination can be resolved as a matter of law — it need not be made by a trier of fact.'" (quoting *Staehr v. Hartford Fin. Servs. Group, Inc.*, 547 F.3d 406, 427 (2d Cir. 2008))). The test for constructive knowledge is objective and "dismissal is appropriate when the facts from which knowledge may be imputed are clear from the pleadings and the public disclosures themselves." *Salinger v. Projectavision, Inc.*, 934 F. Supp. 1402, 1408 (S.D.N.Y. 1996). "The Plaintiffs need not be able to learn the precise details of the fraud, but they must be capable of perceiving the general fraudulent scheme based on the information available to them.... The statute is not tolled for a plaintiff's leisurely discovery of the full details of the alleged scheme. Instead, the period runs from the time at which a plaintiff should have discovered the general fraudulent scheme." *Id.* at 1408–09; *see also In re Integrated Res. Inc. Real Estate Limited P'ships Sec. Litig.*, 850 F. Supp. 1105, 1117–19 (S.D.N.Y. 1993). Thus, for example, the Second Circuit held that the plaintiff utility company's RICO claim accrued as of the time it knew that the defendant manufacturer had delivered defective generators to it. *Long Island Lighting Co. v. Imo Indus., Ind.*, 6 F.3d 876, 887 (2d Cir. 1993). Similarly, where the prospectuses issued to investors contained cautionary language, the Second Circuit held that the existence of such language put the Plaintiffs on inquiry notice that they had been misled by the representations and omissions made by Merrill Lynch to induce them to invest in certain limited partnerships. *In re Merrill Lynch*, 154 F.3d at 60; *see also Town of Poughkeepsie*

v. Espie, 402 F. Supp. 2d 443, 449–50 (S.D.N.Y. 2005) (RICO claim for fraudulent scheme to inflate purchase price of property accrued when the final purchase price was known to the town); *In re Integrated Res.*, 850 F. Supp. at 1119–23 (RICO claims accrued when disclosure documents put Plaintiffs on inquiry notice that prior representations were false).

In the instant case, there can be no doubt that Plaintiffs' RICO claims accrued in 2005. By that time the kits that the labs had purchased from NID had, by Plaintiffs' own admission (Am. Compl. ¶ 59), been recalled by NID. Further, NID had sent recall notices to the members of the putative plaintiff class advising them that the representations NID had made regarding the kits were false, and that in fact the kits did not comport with the Directional Inserts as NID had stated, did not correlate to the industry-standard IRMA kits as NID had represented, and did not have the accuracy and the reliability that NID had promised. Beyond that, the FDA issued public Enforcement Bulletins advising that the kits were defective and had been recalled. Following the recalls, NID further notified its customers that all of its products had been put on hold. Even more powerfully, Defendants issued repeated public filings with the SEC, all available on the Internet, disclosing that the federal government had initiated a *criminal* investigation into the manufacture and sale of the recalled kits. In addition to Defendants' own public disclosure of these facts, the media widely reported the facts regarding the criminal investigation. In sum, the facts establishing the existence of inquiry notice in the instant case are far stronger than the facts that caused the Second Circuit to uphold dismissal of the RICO claims in *In re Merrill Lynch* and *Long Island Lighting Co.*[5/]

[5/] Plaintiffs' reliance on *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-cv-5774, 2009 WL 2043604 (D.N.J. July 10, 2009), in its pre-motion letter is misplaced. Not only is the decision outside of this Circuit, it is inapposite. The court in that case held that the report of a government investigation into off-label marketing standing alone was not sufficient to trigger the statute of limitations. Here, of course, there is much more. As discussed, the commencement of the criminal investigation was accompanied by NID's recall of the defective kits, the sending of recall notices to the purported class members outlining the defects, public disclosure of the recalls and the defects by the FDA, and NID's total hold on all of its products.

As noted, this action was commenced on April 15, 2010. Because there is a four year statute of limitations on Plaintiffs' RICO claims, and because the limitations period on those claims undisputedly began to run in 2005, the First and Second Causes of Action must be dismissed as time-barred.

Finally, Plaintiffs have utterly failed to plead any fraudulent concealment to toll the statute of limitations. At paragraph 5 of the amended complaint, Plaintiffs assert that "the equitable tolling provisions of 28 U.S.C. § 1983 apply." No such statutory provision exists. In a civil RICO case, in order to make out a claim of fraudulent concealment, Plaintiffs would have to plead and prove three necessary elements: (i) wrongful concealment (ii) which prevented discovery of the nature of the claim within the limitations period and (iii) due diligence in pursuing discovery of the claim. *In re Merrill Lynch*, 154 F.3d at 60. Further, such allegation must be pleaded with particularity in accordance with Fed. R. Civ. P. 9(b). *Am. Med. Ass'n v. United Healthcare Corp.*, No. 00 Civ. 2800, 2006 WL 3833440, at *11 (S.D.N.Y. Dec. 29, 2006). Accordingly, Plaintiffs must allege with particularity what Defendants did to conceal material information from them, and why they were unable to discover their claims. *See Rafter v. Liddle*, 704 F. Supp. 2d 370, 377–78 (S.D.N.Y. 2010).

As shown above, just the opposite is the case. Far from concealing material information, in 2005 NID sent multiple recall notices to the members of the putative class recalling the products and outlining how the kits contained defects that varied from the representations that had been made about them. Further, in 2005 NID informed the FDA of the defects and recalls, which agency itself publicly disclosed that information in that year. NID further advised the purported class members in 2005 that it was putting a hold on all of the company's products, which hold was again publicly disclosed in the Form 10-K. And when the United States

Attorney's Office commenced a criminal investigation into the manufacture and sale of the kits, this information was publicly and repeatedly disclosed in the company's SEC filings in 2004 and 2005 as well as by the media. Accordingly, because it cannot be disputed that Defendants hardly "concealed" material information and that Plaintiffs could have discovered the nature of their claim within the limitations period, there can be no tolling of the limitations period.[6/]

B. Plaintiffs' State Law Claims Are Also Time-Barred.

1. Third Cause of Action — Violation of New York General Business Law §§ 349 and 350.

Plaintiffs' claims in the Third Cause of Action for violation of New York General Business Law §§ 349 and 350 are subject to the three-year statute of limitations set forth in New York C.P.L.R. § 214(2). *See Gristede's Foods, Inc. v. Unkechauge Nation*, 532 F. Supp. 2d 439, 452–53 (E.D.N.Y. 2007); *Gaidon v. Guardian Life Ins. Co. of Am.*, 96 N.Y.2d 201, 208 (2001). A cause of action under § 349 accrues "when plaintiff has been injured by a deceptive act or practice violating section 349." *Gaidon*, 96 N.Y.2d at 210. Because, as noted, it is admitted that all defective kits were recalled in 2005 and this action was not commenced until five years later, Plaintiffs' claims are time-barred and must be dismissed.

For the same reasons as discussed above, Plaintiffs cannot assert any grounds for tolling the statute of limitations. In their pre-motion letter Plaintiffs referenced *Kotlyarsky v. N.Y. Post*, 757 N.Y.S.2d 703 (N.Y. Sup. Ct. 2003). However, in that very case the court held that the statute of limitations is *not* tolled "as long as the plaintiff possesses timely knowledge sufficient to place him or her under a duty to make inquiry and ascertain all the relevant facts prior to the

---

6/ Further, in the face of these numerous events that should have sparked diligent inquiry, Plaintiffs allege no action on their part to investigate their claim. This failure to allege their own diligence is itself separately fatal to any "fraudulent concealment" claim. *Simpson v. Putnam County Nat'l Bank of Carmel*,2 0 F. Supp. 2d 630, 635 (S.D.N.Y. 1998).

expiration of the applicable statute of limitations." *Id.* at 707. As shown at length above, it is plain that Plaintiffs here had that timely knowledge.

2. Fourth, Fifth and Sixth Causes of Action — Common Law Fraud.

All of these causes of action assert common law fraud in some form and thus are subject to the limitations period contained in New York C.P.L.R. § 213(8), which requires that such claims be brought within the "greater of six years from the date the cause of action accrued or two years from the time the plaintiff ... discovered the fraud, or could with reasonable diligence have discovered it."[7] Accordingly, Plaintiffs' claims are time-barred except for any claims that accrued between April 15, 2004 and the 2005 recall of the defective kits. For the reasons discussed above, Plaintiffs may not take advantage of the two-year period also referenced in § 213(8).

3. Seventh and Eighth Causes of Action — Breach of Warranty.

Under the Uniform Commercial Code adopted in New York, breach of warranty claims are subject to a four-year statute of limitations. *See* N.Y. U.C.C. LAW § 2-725(1) (McKinney 2001). That statute expressly provides that the breach of warranty claim accrues when tender of delivery of the good is made to the buyer and is not dependent upon a plaintiff's awareness of the defect. *See, e.g.,Gall etta v. Stryker Corp.*, 283 F. Supp. 2d 914, 916 (S.D.N.Y. 2003) (citing *Heller v. U.S. Suzuki Motor Corp.*,64 N.Y.2d 407, 410 (1985)). Inasmuch as it is conceded that all of the alleged defective kits were in fact *recalled* in 2005, it is clear that none of the kits in issue were *delivered* within four years of April 15, 2010, and therefore Plaintiffs' warranty claims are time-barred and must be dismissed.

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[7] Because the Sixth Cause of Action alleging Negligent Misrepresentation depends on the identical alleged acts of misrepresentation that Plaintiffs rely on in the Fourth and Fifth Causes of Action, it is subject to the same limitations period. *Fromer v. Yogel*, 50 F. Supp. 2d 227, 242 (S.D.N.Y. 1999).

Plaintiffs' pre-motion letter suggests that the statute of limitations might not run where a warranty of future performance of a product has been given. This assertion is purely academic here. There is no allegation whatsoever in the amended complaint that any warranty of future performance was ever given with regard to the kits. The law is quite clear: "Where there is no allegation that a warranty for future performance has been made, the statute of limitations for commencing an action for breach of warranty for the sale of goods is four years from the accrual date [i.e., the date of delivery]." *Pahuta v. Massey-Ferguson, Inc.*, 942 F. Supp. 161, 167 (W.D.N.Y. 1996) (internal citations omitted). Moreover, even if a warranty of future performance had been given — which is not even alleged to have occurred here — the statute of limitations is tolled only until the breach was or should have been discovered. *See* N.Y. U.C.C. LAW § 2-725(2). As demonstrated above, it is indisputable that any alleged breach should have been discovered by 2005, when recall notices were sent and all of the kits were recalled. Accordingly, under any possible circumstances, Plaintiffs' breach of warranty claims are time-barred and must be dismissed.

4. Ninth Cause of Action — Unjust Enrichment

Under New York law, "[t]he theory of unjust enrichment lies as a quasi-contract claim." *Gristede's Foods*, 532 F. Supp. 2d at 454. Claims based on implied or express contractual liability are subject to a six-year statute of limitations. N.Y. C.P.L.R. § 213(2). Such claims accrue at the time of breach and "not from the day the breach was discovered, or should have been discovered." *ABB Indus. Sys., Inc. v. Prime Tech., Inc.*,120 F.3d 351, 360 (2d Cir. 1997); *Cunningham v. Ins. Co. of N. Am.*, 521 F. Supp. 2d 166, 170 (E.D.N.Y. 2007) ("'[K]nowledge of the occurrence of the wrong on the part of the plaintiff is not necessary to start the Statute of Limitations running in a contract action.'" (quoting *Ely-Cruickshank Co. v. Bank of Montreal*, 81

N.Y.2d 399, 402 (1993))). Thus, only claims relating to kits sold between April 15, 2004 and the 2005 recall are not time-barred.

V. PLAINTIFFS' STATE LAW AND COMMON LAW CLAIMS FAIL TO STATE A VALID CLAIM FOR RELIEF

A. Third Cause of Action — New York Gen. Bus. Law § 349.

New York Gen. Bus. Law § 349 only protects against direct injuries to consumers. *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc.*, 3 N.Y.3d 200, 206–07 (2004). Plaintiffs never purchased any of the alleged defective kits. Those kits were purchased by clinical laboratories. (Am. Compl. ¶ 28). Plaintiffs seek to represent a class consisting of the laboratories who purchased the kits and by this action are seeking damages resulting from the laboratories' purchase of the kits. *Id.* ¶¶ 6, 10). The Plaintiffs are not laboratories. Their members are not laboratories. Plaintiffs do not reimburse laboratories for the purchase of the kits. Accordingly, with respect to the Plaintiffs, the sale of kits to laboratories is an *indirect injury* which is not reached by § 349 and therefore must be dismissed. *Philip Morris*, 3 N.Y.3d at 206–07 (third party payors of health care costs cannot sue for recovery of costs of service to insureds who were lured into smoking by defendants' violations of § 349).[8/]

Moreover, the alleged false marketing of the kits to the laboratories, which is the basis for Plaintiffs' § 349 allegation, cannot support a claim under the statute, since both the Plaintiffs and the labs are business entities, while the provision only applies to *consumer-oriented* conduct. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 613 (S.D.N.Y. 2005); *Vitolo v.*

[8/] Plaintiffs' reliance on *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 350 (2d Cir. 2003) is misplaced. That case involved a federal court interpretation of a *New Jersey* statute. It has no bearing on the interpretation of New York Gen. Bus. Law § 349, which the New York Court of Appeals definitively interpreted in *Philip Morris*.

Mentor H/S Inc., 426 F. Supp. 2d 28, 34 (E.D.N.Y. 2006).[9/] Thus, for this reason as well the Third Cause of Action fails to state a claim for relief.

Plaintiffs' efforts to invoke the consumer protection statutes of other jurisdictions are unavailing. The named Plaintiffs do not have standing to assert consumer statutes of states where they are not resident. *See, e.g., Gunther v. Capital One,N.A.* , No. 09-cv-2966, 2010 WL 1404122, at *9 (E.D.N.Y. April 8, 2010). Plaintiffs did not even attempt to offer any challenge on this point in their pre-motion letter.

B. Fourth, Fifth and Sixth Causes of Action — Fraud and Misrepresentation Claims.

Plaintiffs' Fourth, Fifth and Sixth Causes of Action for fraud and misrepresentation fail, because each of those claims requires proof of reliance by the plaintiff on the defendant's alleged misrepresentations. *See, e.g., TVT Records v. Island Def Jam Music Group*, 412 F.3d 82, 90–91 (2d Cir. 2005) (fraudulent concealment requires proof of reliance); *Dallas Aerospace, Inc. v. CIS Air Corp.*, 352 F.3d 775, 784 (2d Cir. 2003) (to succeed on claim of fraudulent misrepresentation, plaintiff must prove justifiable reliance on the statement); *Banque Arabe et Internationale D'Investissement v. Md. Nat'l Bank*, 57 F.3d 146, 153 (2d Cir. 1995) (common law fraud claim requires proof that plaintiff reasonably relied upon the representation); *J.A.O. Acquisition Corp. v. Stavitsky*, 8 N.Y.3d 144, 148 (2007) (plaintiff asserting claim of negligent misrepresentation must prove reasonable reliance on the information). Inasmuch as the Plaintiffs themselves never purchased the kits, or even reimbursed the laboratories for their purchases of the kits, there is simply no basis presented for any finding that any alleged marketing misrepresentations by NID regarding the kits were ever made to Plaintiffs or that they ever relied

9/ Plaintiffs' reliance in their pre-motion letter on *Gaidon v. Guardian Life Ins. Co. of Am.*, 94 N.Y.2d 330 (2001), is unavailing. The Plaintiffs in that case were in fact consumers who had themselves purchased "vanishing premium" life insurance policies after receiving deceptive sales pitches. *Id.* at 339.

on any such misrepresentations by NID. Accordingly, in the absence of any plausible averment of reliance, Plaintiffs' fraud and misrepresentation claims must be dismissed. Whether or not the laboratories ever in fact relied on the representations of NID is irrelevant to Plaintiffs' claims here, as it is well-settled that claims of fraud and misrepresentation cannot be based on allegations of third-party reliance. *See, e.g., City of New York v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 454 (2d Cir. 2008), *rev'd on other grounds, Hemi Group, LLC v. City of New York*, 130 S. Ct. 983 (2010).[10/]

C. Seventh and Eighth Causes of Action — Breach of Warranty.

Plaintiffs Seventh and Eighth Causes of Action for breach of warranty fail to state a claim for relief. As a matter of law breach of warranty claims belong solely to the actual purchaser of the goods. *See, e.g.,In re Rezulin*, 392 F. Supp. 2d at 608–09. Because Plaintiffs never purchased the kits, or even reimbursed the laboratories for their purchase of the kits, Plaintiffs' warranty causes of action must be dismissed. Plaintiffs' citation in their pre-motion letter to *Desiano* is wholly inapposite, as nothing in that decision addresses the right of non-purchasers to assert warranty claims.[11/]

D. Ninth Cause of Action — Unjust Enrichment.

Plaintiffs' final claim for unjust enrichment fails to state a claim for relief. This is because Plaintiffs never paid any moneys to NID, neither directly because they never purchased any kits themselves, nor indirectly because they did not reimburse the laboratories for their purchases of the kits from NID. Accordingly, because Plaintiffs never conferred any benefit on

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10/ Plaintiffs' citation in their pre-motion letter to *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), is misplaced, as that case only concerned the issue of whether first party reliance is required under the federal mail fraud statute and has no relevance to the reliance requirement under common law.

11/ Similarly irrelevant is Plaintiffs' reference to *Spencer Trask Software and Information Services LLC v. RPost International, Ltd.*, 383 F. Supp. 2d 428 (S.D.N.Y. 2003), since the Plaintiffs in that case were the direct recipients of the defendants' warranty. *Id.* at 461. Further, unlike the instant action, that case had nothing to do with the purchase of goods, which is governed by the requirements of the UCC that are controlling here.

NID, an essential element of any claim for unjust enrichment, Plaintiffs' Ninth Cause of Action must be dismissed. *See, e.g.*, *Sperry v. Crompton Corp.*, 8 N.Y.3d 204, 215–16 (2007). Plaintiffs' reliance in their pre-motion letter on *Waldman v. New Chapter, Inc.*, 714 F. Supp. 2d 398 (E.D.N.Y. 2010) is misplaced. As noted there, an unjust enrichment claim will not lie where the Plaintiffs' relationship with the defendant is too attenuated. *Id.* at 403. Here, Plaintiffs had no relationship whatsoever with NID. As discussed above, and as Plaintiffs concede (Am. Compl. ¶ 28), NID sold kits to laboratories. Plaintiffs are not labs, their members are not labs, and they did not reimburse the labs for their purchases of the kits. As a result, no claim for unjust enrichment will lie.[12/]

CONCLUSION

For the reasons set forth above, it is respectfully submitted that the amended complaint in this action should be dismissed with prejudice.

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12/ Plaintiffs' citation to *In re Bayer Corp.*, 701 F. Supp. 2d 356 (E.D.N.Y. 2010), is also unavailing, as the Plaintiffs in that case, unlike the Plaintiffs in the instant action, were themselves direct purchasers of the defective product. *Id.* at 364–65.

CERTIFICATE OF SERVICE

I, Seth R. Goldman, certify that pursuant to Section III.D of the Individual Motion Practices of this Court, this Memorandum of Law was served on counsel for the Plaintiffs on February 14, 2011, as follows:

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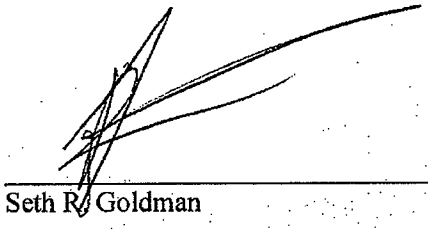

Seth R. Goldman

Exhibit 1

Nichols Institute Diagnostics

March 25, 2005

IMPORTANT – PRODUCT WITHDRAWAL
NICHOLS INSTITUTE DIAGNOSTICS
BIO-INTACT PTH (1-84) ASSAY (Catalog No. 62-7040)
LOT 62-402598

Attention: Laboratory Director

Recent internal testing indicates that Lot 62-402598 of the Nichols Advantage Bio-Intact (1-84) PTH Assay does not meet the following performance specifications stated in the Directional Insert ("DI"): (1) functional sensitivity; (2) reproducibility; (3) parallelism; and (4) interferences.

Nichols Institute Diagnostics ("NID") recommends that customers stop using Lot 62-402598 immediately. Remaining materials should be discarded. Please return the attached form to (1) verify your receipt of the notice, (2) document the amount of product destroyed, and (3) receive credit for the product destroyed.

NID is taking this action based on the results of its internal testing. This action is not the result of customer complaints or reported patient problems.

NID recommends that laboratories act in accordance with their Standard Operating Procedures. The information below is intended to assist laboratories in this evaluation:

A. The DI indicates that PTH tests should be used in conjunction with serum calcium levels and other clinical data to assist the clinician in making patient management decisions.

B. Our testing indicates that laboratories may wish to re-evaluate prior results from Lot 62-402598 that were below 15 pg/mL.

C. **Performance Characteristics of Lot 62-402598**

1. **Functional Sensitivity**: Our testing demonstrates that the **functional sensitivity is below 5.0 pg/mL**. This differs from information in the DI, which states that the estimated Limit of Quantitation (functional sensitivity) is less than 4.0 pg/mL.

2. **Reproducibility**: Our testing demonstrates a **higher %CV** for within-run imprecision and total imprecision than stated in the DI. For samples between 4-1800 pg/mL, the within-run imprecision range is 2.2-20.7% CV, and the total imprecision range is 2.3-25.1% CV. This differs from information in the DI, which provides a recovery range for 4 samples of 2.2-5.5% CV for within-run imprecision and 5.1-10.9% CV for total imprecision.

3. **Parallelism**: Our testing demonstrates a **higher observed dilution % recovery** than the data reported in the DI. For samples with values between 5-1800 pg/mL, the test data show that the mean % recovery is 109%, and the maximum value for any dilution sample is 140%. For samples with values between 50-1800 pg/mL, the test data show that the mean % recovery is 105%, and the maximum value for any dilution sample is 114%. This differs from the information in the DI, which provides a maximum % recovery for any dilution sample of 110%.

4. **Interferences**: Our testing demonstrates performance changes with respect to the hemoglobin and protein interference information stated in the Limitations section of the DI:

(a) **Hemolyzed Samples May Show Over-recovery.** The DI states that grossly hemolyzed samples should not be tested. Our testing demonstrates that samples showing any visible signs of hemolysis should not be tested.

(b) **Interference With Exogenously Added Protein.** Our testing demonstrates that exogenous protein spiked into patient samples over **2000 mg/dL may interfere with the assay,** defined as recovery within ±10% of the control values. This differs from the information in the DI, which states that protein up to 6000 mg/dL (in addition to the endogenous concentration of protein in the sample) does not interfere with the assay defined as recovery within ±10% of the control values.

Please call NID Technical Services at (800) 286-4643, ext. 5222 if you have any questions about this product withdrawal.

NID apologizes for the inconvenience associated with this product withdrawal. The Food and Drug Administration is aware of this action.

Nichols Institute Diagnostics

1311 Calle Batido
San Clemente, California 92673
949.940.7200
800.286.4NID

Nichols Institute Diagnostics

Product Withdrawal Return Response Form

Nichols Advantage® Bio-Intact (1-84) PTH
Catalog #: 62-7040
Lot Number: 62-402598

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the March 25, 2005 letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

☐ I have destroyed withdrawn product.

Any adverse events associated with withdrawn product? ☐ Yes ☐ No
If yes, please explain: _____

_____

_____

Name: _____

Title: _____

Tel. Number: _____

Firm Name: _____

Address: _____

City/State: _____

(PLEASE FAX OR MAIL COMPLETED RESPONSE FORM TO)

Fax Number: (949) 940-7440
Attn. Robert L. Schmidt
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

Nichols Institute Diagnostics

1311 Calle Batido
San Clemente, California 92673
949.940.7200
800.286.4NID

Nichols Institute Diagnostics

Product Withdrawal Return Response Form

Nichols Advantage® Bio-Intact (1-84) PTH
Catalog #: 62-7040
Lot Number: 62-402622

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the March 25, 2005 letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

☐ I have destroyed withdrawn product.

Any adverse events associated with withdrawn product? ☐ Yes ☐ No
If yes, please explain: _____

_____

_____

Name: _____

Title: _____

Tel. Number: _____

Firm Name: _____

Address: _____

City/State: _____

(PLEASE FAX OR MAIL COMPLETED RESPONSE FORM TO)

Fax Number: (949) 940-7440
Attn. Robert L. Schmidt
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

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Nichols Institute Diagnostics

Product Withdrawal Return Response Form

Nichols Advantage® Bio-Intact (1-84) PTH
Catalog #: 62-7040
Lot Number: 62-402622

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the March 25, 2005 letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

☐ I have destroyed withdrawn product.

☐ I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**)

Any adverse events associated with withdrawn product? ☐ Yes ☐ No
If yes, please explain: _____

_____

Name: _____

Title: _____

Tel. Number: _____

Firm Name: _____

Address: _____

City/State: _____

(PLEASE FAX OR MAIL COMPLETED RESPONSE FORM TO)

Fax Number: (949) 940-7440
Attn. Robert L. Schmidt
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

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Nichols Institute
Diagnostics

April 22, 2005

IMPORTANT – PRODUCT WITHDRAWAL

NICHOLS INSTITUTE DIAGNOSTICS
Nichols Advantage ACTH® Cartridge
(Catalog No. 62-7004) lot 62- 500040

Attention: Laboratory Director

Nichols Institute Diagnostics (NID) is informing you that internal testing reflects that the Nichols Advantage ACTH Cartridge lot # 62-500040 does not meet claims in the Directional Insert ("DI") concerning correlation with the IRMA ACTH Assay Catalog # 40-2194.

The Directional Insert states a linear regression formula of $y = 1.02 x + 0.04$ with a population of 115 samples, with IRMA ACTH values ranging from 1.0 to 462 pg/mL. The results of internal testing of lot 62-500040 are $y = 0.72x + 0.04$, $r = 0.99$ with a population of 35 samples, with IRMA ACTH values ranging from 1.0 to 1464 pg/mL.

Nichols Institute Diagnostics ("NID") recommends that customers stop using this Cartridge Lot immediately. Remaining materials should be discarded. Please return the attached form to (1) verify your receipt of the notice, (2) document the amount of product destroyed, and (3) receive credit for the product destroyed.

NID is taking this action based on the results of its internal testing and as a result of customer complaints that the product is not consistent with the method correlation reported in the DI. NID has received no customer complaints of reported patient problems.

NID recommends that laboratories evaluate this information, consult with their medical director, and act in accordance with their Standard Operating Procedures. The DI indicates that ACTH results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

Please call NID Technical Services at (800) 286-4643, ext. 5222 if you have any questions about this product withdrawal. For outside the U.S please contact the appropriate field office (NID Germany at +49(0) 6101.8022.0 or NID France at +33 (0) 1 53.24.99.44) or authorized distributor.

NID apologizes for the inconvenience associated with this product withdrawal.

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Nichols Institute
Diagnostics

April 29, 2005

IMPORTANT – PRODUCT WITHDRAWAL

NICHOLS INSTITUTE DIAGNOSTICS
Nichols Advantage ACTH® Cartridge(Catalog No. 62-7004)
Amendment to April 22 notification:
Withdrawal of lot 62-404296

Attention: Laboratory Director

Nichols Institute Diagnostics (NID) informed you on April 22nd that Nichols Advantage ACTH Cartridge lot # 62-500040 did not meet claims in the Directional Insert ("DI") concerning correlation with the IRMA ACTH Assay Catalog # 40-2194. NID reported that the Directional Insert states a linear regression formula of y = 1.02 x + 0.04 with a population of 115 samples, with IRMA ACTH values ranging from 1.0 to 462 pg/mL. The results of internal testing of lot 62-500040 are y = 0.72x + 0.04, r = 0.99 with a population of 35 samples, with IRMA ACTH values ranging from 1.0 to 1464 pg/mL.

Based on internal testing, lot 62-404296 is expected to perform in a similar manner. NID is therefore withdrawing lot 62-404296.

Nichols Institute Diagnostics ("NID") recommends that customers stop using Cartridge Lot 62-404296 immediately. Remaining materials should be discarded. Please return the attached form to (1) verify your receipt of the notice, (2) document the amount of product destroyed, and (3) receive credit for the product destroyed.

NID is taking this action based on the results of its internal testing and as a result of customer complaints that the product is not consistent with the method correlation reported in the DI. NID has received no customer complaints of reported patient problems.

NID recommends that laboratories evaluate this information, consult with their medical director, and act in accordance with their Standard Operating Procedures. The DI indicates that ACTH results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

Please call NID Technical Services at (800) 286-4643, ext. 5222 if you have any questions about this product withdrawal. For outside the U.S please contact the appropriate field office (NID Germany at +49(0) 6101.8022.0 or NID France at +33 (0) 1 53.24.99.44) or authorized distributor.

NID apologizes for the inconvenience associated with this product withdrawal.

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Nichols Advantage®

IMPORTANT -- PRODUCT NOTIFICATION

Customer Bulletin No. CB-05-17-AD

Date: **April 29, 2005**

Attention: **Laboratory Management**
Nichols Advantage® Operators

Subject: **IMPORTANT PRODUCT NOTIFICATION - Nichols Advantage ACTH Cartridges (Catalog No. 62-7004) lots # 62-304299, 62-304303, 62-400896, 62-403355, 62-403197, and 62-404199.**

Nichols Institute Diagnostics (NID) is informing you that internal testing reflects that the Nichols Advantage ACTH expired Cartridge lots # 62-304299, 62-304303, 62-400896, 62-403355, 62-403197, and 62-404199 may not have met claims in the Directional Insert ("DI") concerning correlation with the IRMA ACTH assay catalog # 40-2194.

The Directional Insert states a linear regression formula of $y = 1.02 x + 0.04$ calculated using 115 samples, with IRMA ACTH values ranging from 1.0 to 462 pg/mL. The results of internal testing indicates as follows:

Lot # of NA ACTH Cartridge	Linear regression formula	Sample Size	Range of IRMA ACTH Values
62-304299	$y = 0.80x + 7.8$	29	7-206 pg/mL
62-400896	$y = 0.89x + 1.6$	50	1-161 pg/mL
62-404199	$y = 0.73x + 0.9$	137	1-383 pg/mL

NID does not have method correlation data for lots 62-304303, 62-403355, and 62-403197. All of the lots covered by this bulletin are expired and should not be in use. NID is providing this information to assist laboratories in evaluating test results.

NID is taking this action based on the results of its internal testing and as a result of customer complaints that the product is not providing results consistent with the method correlation reported in the DI. NID has received no customer complaints of reported patient problems.

NID recommends that laboratories evaluate this information, consult with their medical director, and act in accordance with their Standard Operating Procedures. The DI indicates that ACTH results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

Please contact the Technical Services Department at the numbers listed below if you have questions or need additional information. For the United States call 1-800-286-4NID. For outside the U.S. contact the appropriate field office or authorized distributor

Nichols Institute Diagnostics
Corporate Headquarters

1311 Calle Batido
San Clemente, California 92673
949.940.7200
800.286.4NID
www.nicholsdiag.com

Nichols Institute Diagnostika GmbH

Theodor-Heuss-Str. 52
61118 Bad Vilbel, Germany
Tel. +49 (0) 6101.8022.0
Fax +49 (0) 6101.8022.21

Nichols Institute Diagnostics S.A.R.L.

50 rue de Paradis
75010 Paris, France
Tel. +33 (0) 1 53.24.99.44
Fax +33 (0) 1 53.24.99.45

Exhibit 2

[redacted]

Bulletin

Customer Bulletin No. CB-05-20

Date: June 16, 2005

Attention: Laboratory Director

Subject: IMPORTANT PRODUCT INFORMATION - Product Inventory Hold

This is to advise you of a new quality initiative at Nichols Institute Diagnostics (NID) and an accompanying hold on all products at NID.

As you may know, we have issued customer notifications and product withdrawals for several products in the recent past. In addition, a number of products have been on hold recently due to an issue discovered during an FDA audit.

To assure top quality products, we have decided voluntarily to subject all of NID's assay product lines to an additional quality and regulatory compliance review prior to shipment of products in inventory.

In the short term, this will mean delays in obtaining products, because they will not be available until they go through this additional quality review process.

It will be necessary to carefully consider whether to wait for the release of our products or to seek alternative solutions for your testing needs. We cannot speculate at this time how long the review process may take or when any particular product will become available. We sincerely regret any inconvenience this may cause you and your patients. Our commitment to you is that we will work diligently to complete this quality review. In the long term, we believe the additional quality and regulatory review will help assure that our customers trust NID and the quality of our products.

Please call your local NID Account Manager or NID Customer Service at (800) 286-4NID (4643), ext. 5229, if you have any questions about this product information. For outside the U.S please contact the appropriate field office or authorized distributor.

Thank you for your understanding and support.

Nichols Institute
Diagnostics

Nichols Institute Diagnostics
Corporate Headquarters

1311 Calle Batido
San Clemente, California 92673
949.940.7200
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FORM 10-K

QUEST DIAGNOSTICS INC - DGX

Filed: February 28, 2006 (period: December 31, 2005)

Annual report which provides a comprehensive overview of the company for the past year

SELECTED HISTORICAL FINANCIAL DATA OF OUR COMPANY

The following table summarizes selected historical financial data of our Company and our subsidiaries at the dates and for each of the periods presented. We derived the selected historical financial data for the years 2001 through 2005 from the audited consolidated financial statements of our Company. In April 2002, t . 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections", or SFAS 145. Pursuant to SFAS 145, extraordinary losses associated with the extinguishment of debt in 2001, previously presented net of applicable taxes, were reclassified to other non-operating expenses. In September 2004, the Emerging Issues Task Force reached a final consensus on Issue 04-8, "The Effect of Contingently Convertible Instruments on Diluted Earnings per Share", or Issue 04-8, effective December 31, 2004. Pursuant to Issue 04-8, we included the dilutive effect of our 1¾% contingent convertible debentures issued November 26, 2001 in our dilu lculations using the if-converted method, regardless of whether or not the holders of these securities were permitted to exercise their conversion rights, and retroactively restated previously reported diluted earnings per common share. The selected historical financial data is only a summary and should be read together with the audited consolidated financial statements and related notes of our Company and management's discussion and analysis of financial condition and results of operations included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2005 (a)	2004	2003 (b)	2002 (c)	2001
	(in thousands, except per share data)				
Operations Data:					
Net revenues	$ 5,503,711	$ 5,126,601	$ 4,737,958	$ 4,108,051	$ 3,627,771
Amortization of goodwill (d)	—	—	—	—	38,392
Operating income	968,111 (e)	891,217 (f)	796,454	592,142	411,550
Loss on debt extinguishment	—	—	—	—	42,012 (g)
Net income	546,277 (e),(h)	499,195 (f),(i)	436,717	322,154	162,303 (g)
Basic earnings per common share (j)	$ 2.71	$ 2.45	$ 2.11	$ 1.67	$ 0.87
Diluted earnings per common share (j)(k)	$ 2.66	$ 2.35	$ 2.02	$ 1.59	$ 0.83
Dividends per common share (j)	$ 0.36	$ 0.30	$ 0.075	$ —	$ —
Balance Sheet Data (a):					
Cash and cash equivalents	$ 92,130	$ 73,302	$ 154,958	$ 96,777	$ 122,332
Accounts receivable, net	732,907	649,281	609,187	522,131	508,340
Goodwill, net	3,197,227	2,506,950	2,518,875	1,788,850	1,351,123
Total assets	5,306,115	4,203,788	4,301,418	3,324,197	2,930,555
Long-term debt	1,255,386	724,021	1,028,707	796,507	820,337
Total debt	1,592,225	1,098,822	1,102,657	822,539	821,741
Total stockholders' equity	2,762,984	2,288,651	2,394,694	1,768,863	1,335,987
Other Data:					
Net cash provided by operating activities	$ 851,583	$ 798,780	$ 662,799	$ 596,371	$ 465,803
Net cash used in investing activities	(1,079,793)	(173,700)	(417,050)	(477,212)	(296,616)
Net cash provided by (used in) financing activities	247,038	(706,736)	(187,568)	(144,714)	(218,332)
Provision for doubtful accounts	233,628	226,310	228,222	217,360	218,271
Rent expense	139,660	132,883	120,748	96,547	82,769
Capital expenditures	224,270	176,125	174,641	155,196	148,986
Depreciation and amortization	176,124	168,726	153,903	131,391	147,727

(a) On November 1, 2005, we completed the acquisition of Lab*One*, Inc., or LabOne. Consolidated operating results for 2005 include the results of operations of LabOne subsequent to the closing of the acquisition. See Note 3 to the Consolidated Financial Statements.

(b) On February 28, 2003, we completed the acquisition of Unila la lidated operating results for 2003 include the results of operations of Unilab subsequent to the closing of the acquisition. See Note 3 to the Consolidated Financial Statements.

(c) On April 1, 2002, we completed the acquisition of American Medical Laboratories, Incorporated, or AML. Consolidated operating results for 2002 include the results of operations of AML subsequent to the closing of the acquisition.

(d) In July 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets", or SFAS 142, which we adopted on January 1, 2002. The following table presents net income and basic and diluted earnings per common share data adjusted to exclude the amortization of goodwill, assuming that SFAS 142 had been in effect for the year ended December 31, 2001 (in thousands, except per share data):

	2001
Net income	$ 162,303
Add back: Amortization of goodwill, net of taxes	35,964
Adjusted net income	$ 198,267
Basic earnings per common share	$ 0.87
Amortization of goodwill, net of taxes	0.20
Adjusted basic earnings per common share	$ 1.07
Diluted earnings per common share	$ 0.83
Amortization of goodwill, net of taxes	0.18
Adjusted diluted earnings per common share	$ 1.01

(e) During the third quarter of 2005, we recorded a $6.2 million charge primarily related to forgiveness of amounts owed by patients and physicians, and related property damage as a result of hurricanes in the Gulf Coast. During the fourth quarter of 2005, we recorded a $16 million charge to write-off certain assets in connection with a product hold at NID.

(f) During the second quarter of 2004, we recorded a $10.3 million charge associated with the acceleration of certain pension obligations in connection with the succession of our prior CEO.

(g) In conjunction with our debt refinancing in 2001, we recorded a loss on debt extinguishment of $42 million. The loss represented the write-off of deferred financing costs of $23 million, associated with the debt which was refinanced, and $13 million of payments related primarily to the tender premium incurred in connection with our cash tender offer of our 10¾% senior subordinated notes due 2006. The remaining $6 million of losses represented amounts incurred in conjunction with the cancellation of certain interest rate swap agreements which were terminated in connection with the debt that was refinanced.

(h) During the third quarter of 2005, we recorded a $7.1 million charge associated with the write-down of an investment.

(i) During the second quarter of 2004, we recorded a $2.9 million charge to interest expense, net representing the write-off of deferred financing costs associated with the refinancing of our bank debt and credit facility.

(j) Previously reported basic and diluted earnings per share have been restated to give retroactive effect of our two-for-one stock split effected on June 20, 2005. See Note 2 to the Consolidated Financial Statements.

(k) Potentially dilutive common shares primarily include the dilutive effect of our 1¾% contingent convertible debentures issued November 26, 2001, which were redeemed principally t

-T -Term Incentive Plan.

Exhibit 3

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Safety

Enforcement Report for March 2, 2005

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

March 2, 2005
05-09

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I

PRODUCT
ACME' Sliced Smoked Nova Salmon, NET WT. 8 OZ. (227 g). --- INGREDIENTS: SMOKED SALMON (SALMON, SALT, SUGAR, NATURAL HARDWOODSMOKE, SODIUM NITRITE). The product is packaged in a plastic tub container with a plastic lid. Barcode # 0 23384 10105 7. Recall # F-193-5.
CODE
SELL BY 122404.
RECALLING FIRM/MANUFACTURER
Acme Smoked Fish Corp, Brooklyn, NY, by press release and letter, dated 12/30/04. Firm initiated recall is complete.
REASON
The product was found to be contaminated with Listeria monocytogenes, a pathogenic organism, based on sampling & analysis by the New York State Department of Agriculture & Markets.
VOLUME OF PRODUCT IN COMMERCE
204 , 8 oz. units.
DISTRIBUTION
NY.

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II

PRODUCT
Ultra Flu and Ultra Cap, Nasal Decongestant, Cough Suppressant, Antihistamine, (500 mg acetaminophen, 15 mg dextromethorphan HBr, 2 mg chlorpheniramine maleate) Pain Reliever, Fever Reducer, 25 tablets per bottle, NDC #11383-227-25 and NDC #11383-226-25. Recall # D-133-5.
CODE
Lot #4293, Exp. 9/05.
RECALLING FIRM/MANUFACTURER
Weeks & Leo, Co., Inc., Urbandale, IA, by letter dated December 31, 2004 and by letter and telephone on January 14, 2005. Firm initiated recall is ongoing.
REASON
Labeling: Label lacks the declaration of pseudoephedrine HCl 30 mg.
VOLUME OF PRODUCT IN COMMERCE
2,342/25-tablet bottles.
DISTRIBUTION
Nationwide.

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III

PRODUCT
a) Pramosone cream 1% (hydrocortisone acetate 1%
and pramoxine HCl 1%) packaged in 3 gram
professional sample size metal tubes; Rx only,
NDC 0496-0716-33. Recall # D-134-5;
b) Pramosone cream, 2.5% (hydrocortisone acetate
2.5% and pramoxine HCl 1%), packaged in 3 gram
professional sample size metal tubes; Rx only,
NDC 0496-0717-33. Recall # D-135-5.
CODE
a) Lot 03083B, Exp. 04/05;
b) Lot 030909A, Exp. 04/05;
Lot 03229A, Exp. 10/05 and
Lot 04047A, Exp. 03/06.
RECALLING FIRM/MANUFACTURER
Ferndale Laboratories, Inc., Ferndale, MI, by letters mailed between February 4, 2005 and February 8, 2005. Firm initiated recall is ongoing.
REASON
Defective container: The metal tubes may have pinhole defects, which would result in a super potent product.
VOLUME OF PRODUCT IN COMMERCE
561,260 tubes.
DISTRIBUTION
Nationwide.

PRODUCT
a) Imodium Advanced Caplets (Loperamide HCl 2 mg

Unit numbers: 18FQ91014, 18FQ91018, 18FQ91019, 18FQ91020, 18FQ91021, 18FQ91022, 18FQ91023, 18FQ91024, 18FQ91027, 18FQ91028, 18FQ91029, 18FQ91030, 18FQ91031, 18FQ91032, 18FQ91033, 18FQ91034, 18FQ91035, 18FQ91036, 18GQ91037, 18FQ91038, 18FQ91039, 18FQ91040, 18FQ91042, 18FQ91043, 18FQ91044, 18FQ91046, 18FQ91048, 18GF47000, 18GF47001, 18GF47004, 18GF47005, 18GF47006, 18GF47008, 18GF47010, 18GN26801, 18GN26802, 18GN26804, 18GN26807, 18GN26808, 18GN26810, 18GN26812, 18GN26813, 18GN26815, 18GN26816, 18GN26817, 18GN26818, 18GN26819, 18GN26820, 18GN26821, 18GN26822, 18GN26825, 18GN26827, 18GN26828, 18GN26829, 18GN26830, 18GN26831, 18GN26832, 18GN26833, 18GN26834 and 18GN26835.
RECALLING FIRM/MANUFACTURER
American Red Cross, Great Lakes Region, Lansing, MI, by telephone on December 31, 2003, by facsimile on January 2, 2004, and by letter, dated January 7, 2004. Firm initiated recall is complete.
REASON
Blood products, collected without daily quality control being performed, were distributed.
VOLUME OF PRODUCT IN COMMERCE
60 Units.
DISTRIBUTION
MI and PA.

PRODUCT
Red Blood Cells, Leukocytes Reduced. Recall # B-0690-5.
CODE
Unit number 40LV05536.
RECALLING FIRM/MANUFACTURER
The American National Red Cross, Heart of America Region, Peoria, IL, by telephone on November 29, 2004, and by letter on December 7, 2004. Firm initiated recall is complete.
REASON
Blood product, that did not have the complete amount of additive solution included, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit.
DISTRIBUTION
IL.

PRODUCT
Source Plasma. Recall # B-0699-5.
CODE
Unit 77428554.
RECALLING FIRM/MANUFACTURER
Bio-Blood Components, Inc., Hammond, IN, by facsimile on November 19, 2004. Firm initiated recall is complete.
REASON
Blood product, collected from a donor whose eligibility to donate was not adequately verified, was distributed.
VOLUME OF PRODUCT IN COMMERCE
1 unit.
DISTRIBUTION
CA.

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT
Trinica Bone Tap Instrument, Catalog Number 07.00168.001, sold separately and as part of Zimmer Spine Trinica Anterior Cervical Plating Instrument sets (catalog numbers 07.00215.001 and 07.00546.001). Only the Trinica Bone Tap Instruments are being recalled from the sets. Recall # Z-1014-04.
CODE
Lot P020077.
RECALLING FIRM/MANUFACTURER
Zimmer Spine, Inc., Minneapolis, MN, by letters dated May 25, 2004. Firm initiated recall is ongoing.
REASON
The recalled bone taps could break inside the vertebral body during the tapping process.
VOLUME OF PRODUCT IN COMMERCE
51 units.
DISTRIBUTION
HI, NY, SC, and SD.

PRODUCT
Nichols Advantage 25-Hydroxy Vitamin D Assay, Catalog number 62-7033. Recall # Z-1118-04.
CODE
Not limited to specific lots.
RECALLING FIRM/MANUFACTURER
Nichols Institute Diagnostics, San Clemente, CA, by Customer Bulletin on June 30, 2004. Firm initiated recall is ongoing.
REASON
Lower than expected results are obtained.
VOLUME OF PRODUCT IN COMMERCE
Not specified.
DISTRIBUTION
Nationwide, and Internationally.

PRODUCT
The device generates whole body and head multislice X-ray computed tomography images that are used by the physician in the diagnosis of disease. Brand Name: CT/e; CT/e Dual; CT/e Plus, CT/e Dual Plus; CT/e Lite; ProSpeed AI; ProSpeed AII; ProSpeed FII; ProSpeed EII; CT HiSpeed Series. Recall # Z-0269-05.
CODE
Model or Catalog: 2297024, 2320315, 2244226, 2113694-2, 2115992-4, 2200290-2.
RECALLING FIRM/MANUFACTURER

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Safety

Enforcement Report for May 18, 2005

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

May 18, 2005
05-20

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I

PRODUCT
Golden Lion® Dried Ziziphus Jujuba Mill, net wt. 12 oz. (340g). Product is a dried Chinese red dates packed in a sealed flexible plastic bag. Recall # F-280-5.
CODE
Barcode # 7 34765 04061 1.
RECALLING FIRM/MANUFACTURER
Recalling Firm: Blooming Import Inc., Brooklyn, NY, by press release on October 8, 2004. Manufacturer: Daxin Huafeng Food Co. Ltd., Taishan, China. Firm initiated recall is complete.
REASON
Sampling and analysis by the New York State Department of Agriculture & Markets revealed that the product contained undeclared sulfites (290 ppm).
VOLUME OF PRODUCT IN COMMERCE
72 cases (50 -- 12 oz. packages per case).
DISTRIBUTION
NY, NJ, GA, NC, MD and D.C.

PRODUCT
a) Ziyad Brand Imported Tahini; sesame seed paste packaged in 16 oz., UPC 74265-00156; 32 oz. UPC 74265-00155 (12 jars per case); 64 oz. glass jars, (6 jars per case), UPC 74265-00307; and 128 oz. (4 jars per case) plastic jars, UPC 74265-00093. Recall # F-281-5;
b) Ghandour Tahina 100% Crushed Sesame Seeds; sesame paste packaged in 640 oz. (40 lb.) white plastic pails with green lids and a wire handle; Product of Lebanon. No UPC codes on the containers. Recall # F-282-5.
CODE
There are no lot numbers on the containers. All sizes of all products labeled as Ziyad Brand Imported Tahini are under recall.
RECALLING FIRM/MANUFACTURER
Syrian Bakery Company, Inc., D.B.A., Ziyad Brothers Importing, Cicero, IL, by press release dated April 11, 2005. Firm initiated recall is ongoing.
REASON
Tahini was found contaminated with Salmonella by the Minnesota Dept. of Agriculture, the Illinois Dept. of Public Health, and the FDA.
VOLUME OF PRODUCT IN COMMERCE
35,868 jars and 237 pails.
DISTRIBUTION
Nationwide.

PRODUCT
a) Smoked Atlantic Salmon in 4 oz, 8 oz, 12 oz, 16 oz and larger packages. All flavored varieties listed below were manufactured from the same lot of salmon and various expiration dates. Recall # F-284-5;
b) Moroccan Salmon, one of the flavored varieties. Recall # F-285-5;
c) Smoked Salmon Scampi, one of the flavored varieties. Recall # F-286-5;
d) Salmon Bacon, one of the flavored varieties. Recall # F-287-5;
e) Ming Tsai's 5-Spice Chile Tea Rub Smoked Salmon, one of the flavored varieties. Recall # F-288-5;
f) Salmon Gravelox, one of the flavored varieties. Recall # F-289-5;
g) Czar Cut Salmon Tenderloin. Recall # F-290-5;
h) Pastrami Salmon, one of the flavored varieties. Recall # F-291-5.
CODE
a)- h) Lot 4328 of bulk salmon manufactured into various flavors labeled as Lot 4328 and various expiration dates listed below: 1/29/05, 1/30/05; 1/31/05; 2/01/05; 2/02/05; 2/03/05;

8363R with lot no.'s 11232452, 11209241, 11170011, 11134085, 11044590, 11280218, 11355877A, 11319313, 11362213, 11335475, 11322560, 11277524 and 11221479; Total System TS8275R2 with Lot No.'s 11143684, 11117484, 11113585 and 11078654; Total System TS8287R with Lot no. 11304060; Total System TS8299R with Lot no.'s 11237797 and 11207329; Total System TS8385R with lot no.'s 10890724 and 11157079A; Total System TS8329R3 With Lot no.'s 11319074, 11282455, 11269241, 11260213, 11237174, 11211041, 11355036 and 11326059; Total System TS8339R1 with Lot no.'s 11240930, 1161677 and 11364737; Total System TS8394R1 with Lot no. 11275457; Total System TS8329R3 with Lot no.'s 11454233, 11435228, 11404947 and 11392251; Total System TS8390R with Lot no. 11019052; and Total System TS 8367R1 with Lot no.'s 11247834, 11107184, 11063353, 11033869, 11355872, 11278049 and 11144479.
RECALLING FIRM/MANUFACTURER
Recalling Firm: Medtronic Perfusion Systems, Brooklyn Park, MN, by letters beginning March 25, 2005.
Manufacturer: Medtronic Mexico, S. De R.L. De C.V., Tijuana, Baja California, Mexico. Firm initiated recall is ongoing.
REASON
Some warehouse inventory of Custom Pack product bags were found with ruptured seals. The seals were partially opened in the center of the bag's Tyvek edge. Since this bag is used to enclose and seal the custom pack assembly and had been sterilized, the ruptured seal breaches the sterility barrier for the package.
VOLUME OF PRODUCT IN COMMERCE
4,131 devices (3,373 within US).
DISTRIBUTION
Nationwide and Internationally.

PRODUCT
Nichols IRMA Intact PTH Assay, catalog No. 40-2171. Recall # Z-0809-05.
CODE
Lots 40-504553/4 released March 4, 2005 and kit lots 40-501687/8 released March 18, 2005.
RECALLING FIRM/MANUFACTURER
Nichols Institute Diagnostics, San Clemente, CA, by letters on March 9 and 11, 2005. Firm initiated recall is ongoing.
REASON
Firm noted a change in performance and therefore changed the labeled performance specifications in the Directional Insert portion of the labeling.
VOLUME OF PRODUCT IN COMMERCE
Not divulged.
DISTRIBUTION
Nationwide and Internationally.

PRODUCT
Bio-Intact PTH (1-84) Assay, Catalog No. 62-7040. Recall # Z-0810-05.
CODE
Lots 62-402598 and 62-402622.
RECALLING FIRM
Nichols Institute Diagnostics, San Clemente, CA, by letters dated March 25, 2005. Firm initiated recall is ongoing.
REASON
Values do not agree with Directional Instructions (DI). Lot 62-402598's results were outside the DI claim for functional sensitivity, reproducibility, parallelism and two interfering substances. Lot 62-402622's results were outside the DI claim for functional sensitivity, reproducibility, recovery, parallelism and two interfering substances.
VOLUME OF PRODUCT IN COMMERCE
13,751.
DISTRIBUTION
Nationwide and Internationally.

PRODUCT
The Heartport EndoClamp aortic catheter is a 10.5 Fr. wirewound, three-lumen catheter with an elastomeric balloon near its tip. This device is used with a 200 cm j-hook guide wire accessory device. Product Code EC1001. Recall # Z-0811-05.
CODE
Lot Number, exp. date: MS020434, EXP APRIL-2005; MS0504003, EXP APRIL-2005; MS0504027, EXP MAY-2005; MS0604006, EXP MAY-2005; MS0604007, EXP MAY-2005; MS0704006, EXP JUNE-2005; MS0704015, EXP JUNE-2005; MS0804007, EXP AUGUST-2005; MS1004007, EXP OCTOBER-2005; MS1104021, EXP OCTOBER-2005; MS0105002, EXP JANUARY-2006; MS0105047, EXP FEBRUARY-2006; MS0205039, EXP FEBRUARY-2006; MS0205036, EXP MARCH-2006; MS0205041, EXP MARCH-2006; MS0205042, EXP MARCH-2006.
RECALLING FIRM/MANUFACTURER
Recalling Firm: Heartport, Inc., Somerville, NJ, by telephone on April 8, 2005.
Manufacturer: MedSource Technologies-Laconia, Laconia, NH. Firm initiated recall is ongoing.
REASON
Guidewire is protruding through the film portion of the packages which compromises the sterility of the device.
VOLUME OF PRODUCT IN COMMERCE
1,029 units.
DISTRIBUTION
Nationwide and Internationally.

PRODUCT
a) ENTrak Navigation and Visualization System.
Recall # Z-0812-05;
b) ENTrak Plus Navigation and Visualization System.
Recall # Z-0813-05;
c) InstaTrak 3500 Navigation and Visualization System.
Recall # Z-0814-05;
d) InstaTrak 3500 Plus Navigation and Visualization System.
Recall # Z-0815-05;
CODE
Axcess System Kit P/N: 1005869-001.
RECALLING FIRM/MANUFACTURER
GE OEC Medical Systems, Inc., Salt Lake City, UT, by letter on July 12, 2004. Firm initiated recall is ongoing.
REASON
Navigation inaccuracy may result if the headset registration method is used with the Axcess System Kit.

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U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Safety

Enforcement Report for August 3, 2005

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

August 3, 2005
05-31

RECALLS AND FIELD CORRECTIONS: FOODS AND COSMETICS -- CLASS

PRODUCT
Nabisco 100 Calorie Packs Oreo Thin Crisps Baked Chocolate Wafer Snacks, 4.86 oz. cartons containing six individual serving bags, 6 cartons per case, UPC 446170, Recall # F-544-5
CODE
Best When Used By 04DEC05DD case code 5338BD
RECALLING FIRM/MANUFACTURER
Recalling Firm: Kraft Inc., Northfield, IL, by press release on July 11, 2005.
Manufacturer: Consolidated Biscuit Company, Mc Comb, OH. Firm initiated recall is ongoing.
REASON
Some of the boxes of Nabisco 100 Calorie Packs Oreo Thin Crisps may contain some individual bags of Nabisco 100 Calorie Packs Chips Ahoy Thin Crisps which are made with milk, not declared on the Oreo box.
VOLUME OF PRODUCT IN COMMERCE
17,102 cases
DISTRIBUTION
Nationwide

PRODUCT
a) Beef and Cheese sub sandwich, net wt. 8 oz., EASTSIDE DELI brand, Recall # F-547-5;
b) Beef and Cheese sandwich on wheat bread, net wt. 6 oz., FRESH FROM THE DELI brand, Recall # F-548-5;
c) Ham and cheese submarine sandwich, net wt. 8 oz., EASTSIDE DELI brand, Recall # F-549-5;
d) Ham and swiss on onion sub bun, net wt. 8 oz., EASTSIDE DELI brand, Recall # F-550-5;
e) Ham and cheese sandwich on wheat bread, net wt. 5.5 oz., EASTSIDE DELI brand, Recall # F-551-5;
f) Ham and cheese sandwich on white bread, net wt. 6 oz. or 229 grams, FRESH FROM THE DELI brand, Recall # F-552-5;
g) Ham and cheese sandwich on white sub bun, net wt. 4 oz., In Your Belly Deli brand, Recall # F-553-5;
h) Ham and cheese buddy sandwich on white bun, net wt. 6.5 and 8 oz., EASTSIDE DELI brand, and Fresh from the Deli brand, Recall # F-554-5;
i) Charbroil beef patty sandwich on white bun, net wt. 4.75 oz., In Your Belly Deli brand, Recall # F-555-5;
j) Super beef patty sandwich on white seeded bun, net wt. 5.5 oz., EASTSIDE DELI brand, In Your Belly Deli and FRESH FROM THE DELI brand labels. Recall # F-556-5;
k) Super beef patty on white bun sandwich, net wt. 7 oz., FRESH FROM THE DELI brand, Recall # F-557-5;
l) Gigantic cheeseburger on white seeded bun, 100% ground beef, net wt. 6.5 oz., EASTSIDE DELI brand, Recall # F-558-5;
m) Gigantic beef burger on white seeded bun, 100% pure beef, net wt. 7.5 oz., Fresh from the Deli brand, Recall # F-559-5;
n) 'MEGA' Bacon cheeseburger sandwich on white seeded bun, net wt. 8.5 oz., EASTSIDE DELI brand, Recall # F-560-5;
o) Bacon & Beef Patty sandwich on white seeded bun, Net wt. 7 oz., FRESH FROM THE DELI brand, Recall # F-561-5;

972, 1170, 1171, 1172, 1270 and 1272) pacemaker,
Recall # Z-1034-05;
d) PULSAR MAX II (model nos. 1180, 1181 and 1280)
pacemaker, Recall # Z-1035-05;
e) DISCOVERY II (model nos. 481, 981 1184, 1186, 1187,
1283, 1284, 1285 and 1286) pacemaker,
Recall # Z-1036-05;
f) VIRTUS PLUS II (model nos. 1380 and 1480) pacemaker,
Recall # Z-1037-05;
g) INTELES II (model nos. 1349, 1384, 1385, 1483,
1484, 1485 and 1499) pacemaker, Recall # Z-1038-05;
h) CONTAK TR (model no. 1241) pacemaker,
Recall # Z-1039-05

CODE

a) Model 1174: Serial numbers 109017 thru 115660,
Model 1175: Serial numbers 200731 thru 202199,
Model 1273: Serial numbers 315516 thru 324528,
Model 1274: Serial numbers 296080 thru 496546,
Model 1275: Serial numbers 500705 thru 501661;
b) Model 476: Serial numbers 103316 thru 106064,
Model 976: Serial numbers 202612 thru 205357,
Model 1176: Serial numbers 303330 thru 306689,
and Model 1276: Serial numbers 404640 thru 409060;
c) Model 470: Serial numbers 101150 thru 101894,
Model 870: Serial numbers 200201 thru 201205,
Model 970: Serial numbers 300808 thru 301676,
Model 972: Serial numbers 452959 thru 454562,
Model 1170: Serial numbers 100610 thru 103665,
Model 1171: Serial numbers 300733 thru 302575,
Model 1172: Serial numbers 594273 thru 594437,
Model 1270: Serial numbers 595951 thru 608303,
Model 1272: Serial numbers 600250 thru 600749;
d) Model 1180: Serial numbers 100001 thru 100055,
Model 1181: Serial numbers 300001 thru 300050,
Model 1280: Serial numbers 500003 thru 500525;
e) Model 481: Serial numbers 100000 thru 100115,
Model 981: Serial numbers 200002 thru 200041,
Model 1184: Serial numbers 300012 thru 300061,
Model 1186: Serial numbers 500000 thru 500054,
Model 1187: Serial numbers 450000 thru 450010,
Model 1283: Serial numbers 600001 thru 600073,
Model 1284: Serial numbers 700000 thru 700079,
Model 1286: Serial numbers 900000 thru 900059;
f) Model 1380: Serial numbers 100000 thru 100044,
Model 1480: Serial numbers 500005 thru 500072;
g) Model 1349: Serial numbers 100003 thru 100076,
Model 1384: Serial numbers 300000 thru 300073,
Model 1385: Serial numbers 400005 thru 400019,
Model 1483: Serial numbers 600005 thru 600082,
Model 1484: Serial numbers 700005 thru 700064,
Model 1485: Serial numbers 800005 thru 800053,
Model 1499: Serial numbers 200001 thru 200073;
h) Serial numbers 200128 thru 200479

RECALLING FIRM/MANUFACTURER

Recalling Firm: Guidant Corp-Cpi Division, Saint Paul, MN, by letter dated July 18, 2005.
Manufacturer: Guidant-Ireland, Clomel, Ireland. Firm initiated recall is ongoing.

REASON

A hermetic sealing component utilized in the device may experience a gradual degradation, resulting in a higher than normal moisture content within the pacemeaker case late in the device's service life.

VOLUME OF PRODUCT IN COMMERCE

34,026

DISTRIBUTION

Nationwide and Internationally

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT

Nichols Advantage ACTH Test System, catalog number 62-7004, Recall # Z-1044-05

CODE

Lot numbers: 62-500040 and 62-404296

RECALLING FIRM/MANUFACTURER

Nichols Institute Diagnostics, San Clemente, CA, by letters on April 22 and 29th, 2005. Firm initiated recall is ongoing.

REASON

Performance does not meet claims in the Directional Insert concerning correlation with the IRMA ACTH assay.

VOLUME OF PRODUCT IN COMMERCE

1,599

DISTRIBUTION

Nationwide and Internationally

PRODUCT

Ohmeda Medical?s Giraffe OmniBeds and Giraffe Incubators, Recall # Z-1047-05

Exhibit 4

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarter ended September 30, 2004
Commission file number 1-12215

Quest Diagnostics Incorporated

One Malcolm Avenue
Teterboro, NJ 07608
(201) 393-5000

Delaware
(State of Incorporation)

16-1387862
(I.R.S. Employer Identification Number)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes [X] No [ ]

As of October 26, 2004, there were 101,199,780 outstanding shares of the registrant's common stock, $.01 par value.

PART I - FINANCIAL INFORMATION

On April 30, 2004, the Company repaid the remaining $230 million of principal outstanding under its term loan due June 2007 with $100 million of borrowings under the Credit Facility and $130 million of borrowings under the Secured Receivables Credit Facility.

In conjunction with the debt refinancings, the Company recorded a $2.9 million charge to earnings in the second quarter of 2004 representing the write-off of deferred financing costs associated with the debt that was refinanced. The $2.9 million charge was included in interest expense, net within the consolidated statements of operations for the nine months ended September 30, 2004.

5. COMMITMENTS AND CONTINGENCIES

The Company has standby letters of credit issued under its $68 million letter of credit lines to ensure its performance or payment to third parties, which amounted to $55 million at September 30, 2004. The letters of credit, which are renewed annually, primarily represent collateral for current and future automobile liability and workers' compensation loss payments.

The Company has entered into several settlement agreements with various government and private payers during recent years relating to industry-wide billing and marketing practices that had been substantially discontinued by the mid-1990s. The Company is aware of certain pending lawsuits relating to billing practices filed under the qui tam provisions of the civil False Claims Act and other state and local statutes. Some of the proceedings against the Company involve claims that are substantial in amount.

On October 25, 2004, the Company and its test kit manufacturing subsidiary, Nichols Institute Diagnostics, each received a subpoena from the United States Attorney's office for the Eastern District of New York. The subpoenas seek the production of various business records, including documents related to tests cleared by the Food and Drug Administration for parathyroid hormone, or PTH, levels. The Company intends to cooperate with the government's investigation. Nichols Institute Diagnostics manufactures and markets diagnostic test kits and systems primarily for esoteric testing. These tests are sold principally to hospitals, clinical laboratories and dialysis centers. Quest Diagnostics' net revenues from sales of the PTH test kits and related PTH laboratory testing are estimated to be less than 1% of consolidated net revenues.

In addition, the Company is involved in various legal proceedings arising in the ordinary course of business. Some of the proceedings against the Company involve claims that are substantial in amount.

Although management believes that established reserves for legal matters are sufficient, it is possible that additional information (such as the indication by the government of criminal activity, additional tests being questioned or other changes in the government's or private claimants' theories of wrongdoing) may become available which may cause the final resolution of these matters to exceed established reserves by an amount which could be material to the Company's results of operations and cash flows in the period in which such claims are settled. The Company does not believe that these issues will have a material adverse effect on its overall financial position. However, the Company understands that there may be pending qui tam claims brought by former employees or other "whistle blowers", or other pending claims as to which the Company has not been provided with a copy of the complaint and accordingly cannot determine the extent of any potential liability.

As a general matter, providers of clinical laboratory testing services may be subject to lawsuits alleging negligence or other similar legal claims. These suits could involve claims for substantial damages. Any professional liability litigation could also have an adverse impact on the Company's client base and reputation. The Company maintains various liability insurance programs for claims that could result from providing or failing to provide clinical laboratory testing services, including inaccurate testing results and other exposures. The Company's insurance coverage limits its maximum exposure on individual claims; however, the Company is essentially self-insured for a significant portion of these claims. The basis for claims reserves incorporates actuarially determined losses based upon the Company's historical and projected loss experience. Management believes that present insurance coverage and reserves are sufficient to cover currently estimated exposures. Although management cannot predict the outcome of any claims made against the Company, management does not anticipate that the ultimate outcome of any such proceedings or claims will have a material adverse effect on the Company's financial position but may be material to the Company's results of operations and cash flows in the period in which such claims are resolved.

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FORM 10-K

QUEST DIAGNOSTICS INC - DGX

Filed: March 10, 2005 (period: December 31, 2004)

Annual report which provides a comprehensive overview of the company for the past year

have also applied to Medicaid-covered services. Many states have similar anti-"self-referral" and other laws that are not limited to Medicare and Medicaid referrals and could also affect investment and compensation arrangements with physicians. We cannot predict if some of the state laws will be interpreted contrary to our practices.

In April 2003, the OIG issued a Special Advisory Bulletin addressing what it described as "questionable contractual arrangements" in contractual joint ventures. The OIG Bulletin focused on arrangements where a healthcare provider, or Owner, expands into a related healthcare business by contracting with a healthcare provider, or Manager, that already is engaged in that line of business for the Manager to provide related healthcare items or services to the patients of the Owner in return for a share of the profits of the new line of business. While we believe that the Bulletin is directed at "sham" arrangements intended to induce referrals, we cannot predict whether the OIG might choose to investigate all contractual joint ventures, including our joint ventures with various hospitals or hospital systems.

Government Investigations and Related Claims

We are subject to extensive and frequently changing federal, state and local laws and regulations. We believe that, based on our experience with government settlements and public announcements by various government officials, the federal government continues to strengthen its position on healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse give federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected cases of fraud and abuse. Many of the regulations applicable to us, including those relating to billing and reimbursement of tests and those relating to relationships with physicians and hospitals, are vague or indefinite and have not been interpreted by the courts. They may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations, including our billing practices. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, including the loss of licenses or our ability to participate in Medicare, Medicaid and other federal and state healthcare programs. In addition, certain federal and state statues, including the qui tam provisions of the federal False Claim Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government or private payers alleging inappropriate billing practices.

During the mid-1990s, Quest Diagnostics and SBCL settled significant government claims that primarily involved industry-wide billing and marketing practices that both companies believed to be lawful. The federal or state governments may bring additional claims based on new theories as to our practices that we believe to be in compliance with law. The federal government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs, which represented approximately 17% of our net revenues during 2004.

There are certain pending lawsuits regarding our billing practices filed under the qui tam provisions of the federal false claims statute and other federal and state statutes. Some of the cases involve claims that are substantial in amount. We have also received subpoenas from the United States Attorney's Office for the Eastern District of New York requiring the production of various business records including documents related to parathyroid hormone testing and parathyroid hormone test kits manufactured by our subsidiary Nichols Institute Diagnostics. We are cooperating with the government's investigation.

Although management believes that established reserves for claims are sufficient, including qui tam cases, of which management is aware, it is possible that additional information may become available that may cause the final resolution of these matters to exceed established reserves by an amount which could be material to our results of operations and cash flows in the period in which such claims are settled. We do not believe that these issues will have a material adverse effect on our overall financial condition. However, we understand that there may be pending qui tam claims brought by former employees or other "whistle blowers" as to which we have not been provided with a copy of the complaint and accordingly cannot determine the extent of any potential liability.

As an integral part of our compliance program discussed below, we investigate all reported or suspected failures to comply with federal healthcare reimbursement requirements. Any non-compliance that results in Medicare or Medicaid overpayments is reported to the government and reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments. While we have reimbursed these overpayments and have taken corrective action where appropriate, we cannot assure investors that in each instance the government will necessarily accept these actions as sufficient.

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FORM 10-K

QUEST DIAGNOSTICS INC - DGX

Filed: February 28, 2006 (period: December 31, 2005)

Annual report which provides a comprehensive overview of the company for the past year

Fraud and Abuse Regulations. Medicare and Medicaid anti-kickback laws prohibit clinical laboratories from making payments or furnishing other benefits to influence the referral of tests billed to Medicare, Medicaid or other federal programs. As noted above, the penalties for violation of these laws may include criminal and civil fines and penalties and/or suspension or exclusion from participation in federal programs. Many of the anti-fraud statutes and regulations, including those relating to joint ventures and alliances, are vague or indefinite and have not been interpreted by the courts. We cannot predict if some of the fraud and abuse rules will be interpreted contrary to our practices.

In November 1999, the OIG issued an advisory opinion concluding that the industry practice of discounting client bills may constitute a kickback if the discounted price is below a laboratory's overall cost (including overhead) and below the amounts reimbursed by Medicare. Advisory opinions are not binding but may be indicative of the position that prosecutors may take in enforcement actions. The OIG's opinion, if enforced, could result in fines and possible exclusion and could require us to eliminate offering discounts to clients below the rates reimbursed by Medicare. The OIG subsequently issued a letter clarifying that it did not intend to imply that discounts are a per se violation of the federal anti-kickback statute, but may merit further investigation depending on the facts and circumstances presented.

In addition, since 1992, a federal anti-"self-referral" law, commonly known as the "Stark" law, prohibits, with certain exceptions, Medicare payments for laboratory tests referred by physicians who have personally, or through a family member, an investment interest in, or a compensation arrangement with, the testing laboratory. Since January 1995, these restrictions have also applied to Medicaid-covered services. Many states have similar anti-"self-referral" and other laws that are not limited to Medicare and Medicaid referrals and could also affect investment and compensation arrangements with physicians. We cannot predict if some of the state laws will be interpreted contrary to our practices.

In April 2003, the OIG issued a Special Advisory Bulletin addressing what it described as "questionable contractual arrangements" in contractual joint ventures. The OIG Bulletin focused on arrangements where a healthcare provider, or Owner, expands into a related healthcare business by contracting with a healthcare provider, or Manager, that already is engaged in that line of business for the Manager to provide related healthcare items or services to the patients of the Owner in return for a share of the profits of the new line of business. While we believe that the Bulletin is directed at "sham" arrangements intended to induce referrals, we cannot predict whether the OIG might choose to investigate all contractual joint ventures, including our joint ventures with various hospitals or hospital systems.

Government Investigations and Related Claims

We are subject to extensive and frequently changing federal, state and local laws and regulations. We believe that, based on our experience with government settlements and public announcements by various government officials, the federal government continues to strengthen its position on healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse give federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected cases of fraud and abuse. Many of the regulations applicable to us, including those relating to billing and reimbursement of tests and those relating to relationships with physicians and hospitals, are vague or indefinite and have not been interpreted by the courts. They may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations, including our billing practices. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, including the loss of licenses or our ability to participate in Medicare, Medicaid and other federal and state healthcare programs and additional liabilities from third party claims. In addition, certain federal and state statues, including the qui tam provisions of the federal False Claim Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government or private payers alleging inappropriate billing practices.

During the mid-1990s, Quest Diagnostics and SBCL settled significant government claims that primarily involved industry-wide billing and marketing practices that both companies believed to be lawful. The federal or state governments may bring additional claims based on new theories as to our practices that we believe to be in compliance with law. The federal government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs, which represented approximately 18% of our net revenues during 2005.

We understand that there may be pending qui tam claims brought by former employees or other "whistle blowers" as to which we have not been provided with a copy of the complaint and accordingly cannot determine the extent of any potential liability. We are also aware of certain pending lawsuits related to billing practices filed under the qui tam provisions of the civil False Claims Act and other federal and state statutes. These lawsuits include class action and individual claims by patients arising out of the Company's billing policies. In addition, we are involved in various legal proceedings arising in the ordinary course of business. Some of the proceedings against us involve claims that are substantial in amount.

During the fourth quarter of 2004, Quest Diagnostics Incorporated and Nichols Institute Diagnostics (NID), our test kit manufacturing subsidiary, each received a subpoena from the United States Attorney's Office for the Eastern District of New York. Quest Diagnostics and NID have been cooperating with the United States Attorney's Office. In connection with such cooperation, we have been providing information and producing various business records of NID and Quest Diagnostics, including documents related to testing and test kits manufactured by NID. This investigation by the United States Attorney's Office could lead to civil and criminal damages, fines and penalties and additional liabilities from third party claims. In the second and third quarters of 2005, the FDA conducted an inspection of NID and issued a Form 483 listing the observations made by the FDA during the course of the inspection. NID is cooperating with the FDA and has filed its responses to the Form 483. Noncompliance with the FDA regulatory requirements or failure to take adequate and timely corrective action could lead to regulatory or enforcement action against NID and/or Quest Diagnostics, including, but not limited to, a warning letter, injunction, suspension of production and/or distribution, seizure or recall of products, fines or penalties, denial of pre-market clearance for new or changed products, recommendation against award of government contracts and criminal prosecution.

During the second quarter of 2005, we received a subpoena from the United States Attorney's Office for the District of New Jersey. The subpoena seeks the production of business and financial records regarding capitation and risk sharing arrangements with government and private payers for the years 1993 through 1999. Also, during the third quarter of 2005, we received a subpoena from the U.S. Department of Health and Human Services, Office of the Inspector General. The subpoena seeks the production of various business records including records regarding our relationship with health maintenance organizations, independent physician associations, group purchasing organizations, and preferred provider organizations from 1995 to the present. We are cooperating with the United States Attorney's Office and the Office of the Inspector General.

Although management cannot predict the outcome of such matters, management does not anticipate that the ultimate outcome of such matters will have a material adverse effect on our financial condition, but may be material to our results of operations and cash flows in the period in which the impact of such matters is determined or paid.

As an integral part of our compliance program discussed below, we investigate all reported or suspected failures to comply with federal and state healthcare reimbursement requirements. Any non-compliance that results in Medicare or Medicaid overpayments is reported to the government and reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments. While we have reimbursed these overpayments and have taken corrective action where appropriate, we cannot assure investors that in each instance the government will necessarily accept these actions as sufficient.

Compliance Program

Compliance with all government rules and regulations has become a significant concern throughout the clinical laboratory industry because of evolving interpretations of regulations and the emerging changes in laboratory science and healthcare technology. We established a compliance program early in 1993.

We emphasize the development of training programs intended to ensure the strict implementation and observance of all applicable laws, regulations and Company policies. Further, we conduct in-depth reviews of procedures, personnel and facilities to assure regulatory compliance throughout our operations. The Quality, Safety & Compliance Committee of the Board of Directors requires periodic reporting of compliance operations from management.

We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. Many of these statutes and regulations have not been interpreted by the courts. We cannot assure investors that applicable statutes or regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect us. Potential sanctions for violation of these statutes include significant damages, penalties, and fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorization necessary to operate some or all of our business, which could have a material adverse effect on our business.

Intellectual Property Rights

Other companies or individuals, including our competitors, may obtain patents or other property rights that would prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business. As a result, we may be involved in intellectual property litigation and we may be found to infringe on the proprietary rights of others, which could force us to do one or more of the following:

- cease developing, performing or selling products or services that incorporate the challenged intellectual property;
- obtain and pay for licenses from the holder of the infringed intellectual property right;

Exhibit 5

10/28/04 Reuters News 13:21:30

Reuters News

October 28, 2004

Quest Diagnostics gets subpoenas over test

CHICAGO, Oct 28 (Reuters) - QuestDiagnostics Inc.<DGX.N> said on Thursday it received subpoenas as part of a widespread justice department **investigation** into use of tests and drugs for patients with kidney disease.

Quest said it received subpoenes regarding a test kit for parathyroid hormone made by its Nichols Institute Diagnostics unit. The subpoenas were issued by the U.S. attorney in New York. Quest said it will cooperate with the **investigation**.

Quest is the latest in a series of companies to recieve subpoenas in the probe. To date, Fresenius Medical Care <FMEG.DE> of Germany and U.S. companies DaVita Inc.<DVA.N> and Renal Care Group Inc.<RCI.N> have received subpoenas in the probe, which may involve both civil and criminal charges.

((Reporting by Julie Steenhuysen, editing by Martin Golan; Reuters Messaging: julie.steenhuysen.reuters.com@reuters.net; julie.steenhuysen@reuters.com; 312-408-8131))

---- INDEX REFERENCES ---

COMPANY: FRESENIUS MEDICAL CARE; DAVITA INC; FRESENIUS MEDICAL CARE AG AND CO KGAA; QUEST DIAGNOSTICS INC; NICHOLS INSTITUTE DIAGNOSTICS

INDUSTRY: (Clinical Laboratory (1CL83); Healthcare Services (1HE13); Healthcare (1HE06); Pharmaceuticals & Biotechnology (1PH13); Clinical Diagnostics (1DI45))

REGION: (North America (1NO39); Americas (1AM92); USA (1US73))

Language: EN

OTHER INDEXING: (AND RENAL CARE GROUP INC; DAVITA INC; FRESENIUS MEDICAL CARE; NICHOLS INSTITUTE DIAGNOSTICS; QUEST DIAGNOSTICS; QUEST DIAGNOSTICS INC) (Julie Steenhuysen; Martin Golan; Quest; Republication)

Word Count: 250
10/28/04 REUTERS 13:21:30
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10/29/04 Star-Ledger (Newark N.J.) 46
2004 WLNR 20258254
Star-Ledger, The (Newark, NJ)

October 29, 2004

Section: BUSINESS

GARDEN STATE BRIEFS

IDT chairman's political

Corporate executives donate lots of money to political candidates, but few make public endorsements when the outcome of an election is in doubt. It can alienate customers, and make matters difficult if a company's leaders back the losing side. That hasn't stopped IDT Chairman Howard Jonas from supporting President Bush in ads that appear today in The Star-Ledger and other newspapers.

Jonas, who helped raise millions for Bush this year in his role as finance co-chair of the Republican National Convention's host committee, said the administration shares credit for the success of IDT, a Newark-based telecommunications company that has grown dramatically in recent years.

"It wouldn't have happened if there were another four years of Clinton," he said.

Jonas is picking up the tab for the ads, not IDT. He said he is targeting New Jersey because Bush still has a shot at carrying the state, even though he is trailing in the polls here.

"I still don't believe he'll win in the state," Jonas said, "but you never know." - Jeff May

Lawyers switch firms

A prominent criminal defense lawyer is leaving the Middlesex County firm where he is a name partner to join Lowenstein Sandler in Roseland, officials said yesterday.

Starting Monday, Michael Himmel and two other partners from Greenbaum, Rowe, Smith, Ravin, Davis & Himmel in Woodbridge will be partners at the state's second-largest firm. The other lawyers are Robert Kipnees and Christopher Porrino. Himmel will serve as chair of the white-collar criminal defense practice group.

Lowenstein's managing partner, Michael Rodburg, said the additions would bring more name recognition to its white collar practice.

A former federal prosecutor, Himmel has served as president of the Association of the Federal Bar for the State of New Jersey.

Himmel said he was compelled to move because he could not pass up the opportunity to work at a firm with a Manhattan office. - Kate Coscarelli

Horizon opens office

Horizon Blue Cross Blue Shield of New Jersey opened an office building in Wall Township that will initially house 800 employees and may eventually grow to 1,000.

The facility will house a call center, mail processing operations and customer service employees. It also will serve as a backup center in case of disruption at the company's headquarters in Newark.

About 10 jobs from Newark will be moved to the facility, a spokesman said.

Horizon is the state's largest health insurer, providing coverage to more than 2.9 million people. - Tom Johnson

Economic outlook

The Federal Reserve Bank of Philadelphia expects New Jersey's economy to grow about 3 percent over the next three quarters, about the same rate it has been expanding since the beginning of 2004.

The regional bank said, based on economic data collected in September, its growth estimate for the next nine months was down slightly from last month's 3.4 percent forecast.

"That's not a significant change," and is within typical statistical variation, said economist Ted Crone, a vice president of the bank. - Associated Press

Quest subpoenas

Quest Diagnostics, a leading marketer of diagnostic tests and services, said it had received subpoenas as part of a U.S. Justice Department **investigation** into the use of tests and drugs for patients with kidney disease.

The Teterboro-based company also said its **Nichols** Institute **Diagnostics** unit received a subpoena from the U.S.

Attorney in New York. The subpoenas seek business records, including those related to tests for parathyroid hormone levels.

Quest, which said it will cooperate with the investigation, said the tests made by Nichols are sold principally to hospitals, clinical laboratories and dialysis centers. Sales generated by these kits and related testing are estimated at less than 1 percent of its consolidated revenue. - Ed Silverman

Pfizer OKs buyback

Pfizer, the world's largest drug maker, said its board of directors authorized the buyback of up to $5 billion of the company's common shares.

Pfizer, which has extensive operations in New Jersey, said it expects to buy back the shares by the end of 2005. The company said it recently completed a $5 billion buyback the board authorized last December. The company's market capitalization exceeds $210 billion, based on the 7.55 billion shares outstanding as of Aug. 4. - Reuters

And finally . . .

Valley National Bank has opened a new branch on West Union Avenue in Bound Brook. . . . Defense contractor DRS Technologies , based in Parsippany, said it received $39.5 million in orders to provide rugged appliqu? computer systems for the Army's Force 21 battle command, brigade and below program. - Staff and wire reports

---- INDEX REFERENCES ---

COMPANY: FEDERAL RESERVE SYSTEM; PFIZER INC; VALLEY NATIONAL CORP; QUEST DIAGNOSTICS INC

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